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Contents

Federal Register

Vol. 80, No. 215

Friday, November 6, 2015

Separate Parts In This Issue

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Administrative Orders:

Memorandums:

Memorandum of November 3, 2015 68743

10 CFR

433.....68749

12 CFR

Proposed Rules:

327.....68780

14 CFR

97 (4 documents) 68758, 68759, 68761, 68763

15 CFR

301 (2 documents) 68765

303.....68765

26 CFR

Proposed Rules:

1.....68794

29 CFR

Proposed Rules:

29.....68908

30.....68908

38 CFR

Proposed Rules:

74.....68795

40 CFR

52 (2 documents) 68766, 68768

180.....68772

Proposed Rules:

52.....68807

60.....68808

180.....69080

42 CFR

413.....68968

47 CFR

Proposed Rules:

1.....68815

25.....68815

73.....68815

74.....68815

48 CFR

1817.....68778

1852.....68778

50 CFR

665.....68778

Federal Register
Vol. 80, No. 215
Friday, November 6, 2015

Presidential Documents

Title 3—

The President

Memorandum of November 3, 2015

Mitigating Impacts on Natural Resources From Development and Encouraging Related Private Investment

Memorandum for the Secretary of Defense[,] the Secretary of the Interior[,] the Secretary of Agriculture[,] the Administrator of the Environmental Protection Agency[, and] the Administrator of the National Oceanic and Atmospheric Administration

We all have a moral obligation to the next generation to leave America's natural resources in better condition than when we inherited them. It is this same obligation that contributes to the strength of our economy and quality of life today. American ingenuity has provided the tools that we need to avoid damage to the most special places in our Nation and to find new ways to restore areas that have been degraded.

Federal agencies implement statutes and regulations that seek simultaneously to advance our economic development, infrastructure, and national security goals along with environmental goals. As efforts across the country have demonstrated, it is possible to achieve strong environmental outcomes while encouraging development and providing services to the American people. This occurs through policies that direct the planning necessary to address harmful impacts on natural resources by avoiding and minimizing impacts, then compensating for impacts that do occur. Moreover, when opportunities to offset foreseeable harmful impacts to natural resources are available in advance, agencies and project proponents have more options to achieve positive environmental outcomes and potentially reduce permitting timelines.

Federal agencies can, however, face barriers that hinder their ability to use Federal resources for restoration in advance of regulatory approval of development and other activities (e.g., it may not be possible to fund restoration before the exact location and scope of a project have been approved; or there may be limitations in designing large-scale management plans when future development is uncertain). This memorandum will encourage private investment in restoration and public-private partnerships, and help foster opportunities for businesses or non-profit organizations with relevant expertise to successfully achieve restoration and conservation objectives.

One way to increase private investment in natural resource restoration is to ensure that Federal policies are clear, work similarly across agencies, and are implemented consistently within agencies. By encouraging agencies to share and adopt a common set of their best practices to mitigate for harmful impacts to natural resources, the Federal Government can create a regulatory environment that allows us to build the economy while protecting healthy ecosystems that benefit this and future generations. Similarly, in non-regulatory circumstances, private investment can play an expanded role in achieving public natural resource restoration goals. For example, performance contracts and other Pay for Success approaches offer innovative ways to finance the procurement of measurable environmental benefits that meet high government standards by paying only for demonstrated outcomes.

Therefore, by the authority vested in me as President by the Constitution and the laws of the United States of America, and to protect the health of our economy and environment, I hereby direct the following:

Section 1. *Policy*. It shall be the policy of the Departments of Defense, the Interior, and Agriculture; the Environmental Protection Agency; and

the National Oceanic and Atmospheric Administration; and all bureaus or agencies within them (agencies); to avoid and then minimize harmful effects to land, water, wildlife, and other ecological resources (natural resources) caused by land- or water-disturbing activities, and to ensure that any remaining harmful effects are effectively addressed, consistent with existing mission and legal authorities. Agencies shall each adopt a clear and consistent approach for avoidance and minimization of, and compensatory mitigation for, the impacts of their activities and the projects they approve. That approach should also recognize that existing legal authorities contain additional protections for some resources that are of such irreplaceable character that minimization and compensation measures, while potentially practicable, may not be adequate or appropriate, and therefore agencies should design policies to promote avoidance of impacts to these resources.

Large-scale plans and analysis should inform the identification of areas where development may be most appropriate, where high natural resource values result in the best locations for protection and restoration, or where natural resource values are irreplaceable. Furthermore, because doing so lowers long-term risks to our environment and reduces timelines of development and other projects, agency policies should seek to encourage advance compensation, including mitigation bank-based approaches, in order to provide resource gains before harmful impacts occur. The design and implementation of those policies should be crafted to result in predictability sufficient to provide incentives for the private and non-governmental investments often needed to produce successful advance compensation. Wherever possible, policies should operate similarly across agencies and be implemented consistently within them.

To the extent allowed by an agency's authorities, agencies are encouraged to pay particular attention to opportunities to promote investment by the non-profit and private sectors in restoration or enhancement of natural resources to deliver measurable environmental outcomes related to an established natural resource goal, including, if appropriate, as part of a restoration plan for natural resource damages or for authorized investments made on public lands.

Sec. 2. *Definitions*. For the purposes of this memorandum:

(a) ''Agencies'' refers to the Department of Defense, Department of the Interior, Department of Agriculture, Environmental Protection Agency, and National Oceanic and Atmospheric Administration, and any of their respective bureaus or agencies.

(b) ''Advance compensation'' means a form of compensatory mitigation for which measurable environmental benefits (defined by performance standards) are achieved before a given project's harmful impacts to natural resources occur.

(c) ''Durability'' refers to a state in which the measurable environmental benefits of mitigation will be sustained, at minimum, for as long as the associated harmful impacts of the authorized activity continue. The ''durability'' of a mitigation measure is influenced by: (1) the level of protection or type of designation provided; and (2) financial and long-term management commitments.

(d) ''Irreplaceable natural resources'' refers to resources recognized through existing legal authorities as requiring particular protection from impacts and that because of their high value or function and unique character, cannot be restored or replaced.

(e) ''Large-scale plan'' means any landscape- or watershed-scale planning document that addresses natural resource conditions and trends in an appropriate planning area, conservation objectives for those natural resources, or multiple stakeholder interests and land uses, or that identifies priority sites for resource restoration and protection, including irreplaceable natural resources.

(f) ''Mitigation'' means avoiding, minimizing, rectifying, reducing over time, and compensating for impacts on natural resources. As a practical matter, all of these actions are captured in the terms avoidance, minimization, and compensation. These three actions are generally applied sequentially, and therefore compensatory measures should normally not be considered until after all appropriate and practicable avoidance and minimization measures have been considered.

Sec. 3. *Establishing Federal Principles for Mitigation*. To the extent permitted by each agency's legal authorities, in addition to any principles that are specific to the mission or authorities of individual agencies, the following principles shall be applied consistently across agencies to the extent appropriate and practicable.

(a) Agencies should take advantage of available Federal, State, tribal, local, or non-governmental large-scale plans and analysis to assist in identifying how proposed projects potentially impact natural resources and to guide better decision-making for mitigation, including avoidance of irreplaceable natural resources.

(b) Agencies' mitigation policies should establish a net benefit goal or, at a minimum, a no net loss goal for natural resources the agency manages that are important, scarce, or sensitive, or wherever doing so is consistent with agency mission and established natural resource objectives. When a resource's value is determined to be irreplaceable, the preferred means of achieving either of these goals is through avoidance, consistent with applicable legal authorities. Agencies should explicitly consider the extent to which the beneficial environmental outcomes that will be achieved are demonstrably new and would not have occurred in the absence of mitigation (i.e. additionality) when determining whether those measures adequately address impacts to natural resources.

(c) With respect to projects and decisions other than in natural resource damage cases, agencies should give preference to advance compensation mechanisms that are likely to achieve clearly defined environmental performance standards prior to the harmful impacts of a project. Agencies should look for and use, to the extent appropriate and practicable, available advance compensation that has achieved its intended environmental outcomes. Where advance compensation options are not appropriate or not available, agencies should give preference to other compensatory mitigation practices that are likely to succeed in achieving environmental outcomes.

(d) With respect to natural resource damage restoration plans, natural resource trustee agencies should evaluate criteria for whether, where, and when consideration of restoration banking or advance restoration projects would be appropriate in their guidance developed pursuant to section 4(d) of this memorandum. Consideration under established regulations of restoration banking or advance restoration strategies can contribute to the success of restoration goals by delivering early, measurable environmental outcomes.

(e) Agencies should take action to increase public transparency in the implementation of their mitigation policies and guidance. Agencies should set measurable performance standards at the project and program level to assess whether mitigation is effective and should clearly identify the party responsible for all aspects of required mitigation measures. Agencies should develop and use appropriate tools to measure, monitor, and evaluate effectiveness of avoidance, minimization, and compensation policies to better understand and explain to the public how they can be improved over time.

(f) When evaluating proposed mitigation measures, agencies should consider the extent to which those measures will address anticipated harm over the long term. To that end, agencies should address the durability of compensation measures, financial assurances, and the resilience of the measures' benefits to potential future environmental change, as well as ecological relevance to adversely affected resources.

(g) Each agency should ensure consistent implementation of its policies and standards across the Nation and hold all compensatory mitigation mechanisms to equivalent and effective standards when implementing their policies.

(h) To improve the implementation of effective and durable mitigation projects on Federal land, agencies should identify, and make public, locations on Federal land of authorized impacts and their associated mitigation projects, including their type, extent, efficacy of compliance, and success in achieving performance measures. When compensatory actions take place on Federal lands and waters that could be open to future multiple uses, agencies should describe measures taken to ensure that the compensatory actions are durable.

Sec. 4. *Federal Action to Strengthen Mitigation Policies and Support Private Investment in Restoration*. In support of the policy and principles outlined above, agencies identified below shall take the following specific actions.

(a) Within 180 days of the date of this memorandum, the Department of Agriculture, through the U.S. Forest Service, shall develop and implement additional manual and handbook guidance that addresses the agency's approach to avoidance, minimization, and compensation for impacts to natural resources within the National Forest System. The U.S. Forest Service shall finalize a mitigation regulation within 2 years of the date of this memorandum.

(b) Within 1 year of the date of this memorandum, the Department of the Interior, through the Bureau of Land Management, shall finalize a mitigation policy that will bring consistency to the consideration and application of avoidance, minimization, and compensatory actions or development activities and projects impacting public lands and resources.

(c) Within 1 year of the date of this memorandum, the Department of the Interior, through the U.S. Fish and Wildlife Service, shall finalize a revised mitigation policy that applies to all of the U.S. Fish and Wildlife Service's authorities and trust responsibilities. The U.S. Fish and Wildlife Service shall also finalize an additional policy that applies to compensatory mitigation associated with its responsibilities under the Endangered Species Act of 1973. Further, the U.S. Fish and Wildlife Service shall finalize a policy that provides clarity to and predictability for agencies and State governments, private landowners, tribes, and others that take action to conserve species in advance of potential future listing under the Endangered Species Act. This policy will provide a mechanism to recognize and credit such action as avoidance, minimization, and compensatory mitigation.

(d) Within 1 year of the date of this memorandum, each Federal natural resource trustee agency will develop guidance for its agency's trustee representatives describing the considerations for evaluating whether, where, and when restoration banking or advance restoration projects would be appropriate as components of a restoration plan adopted by trustees. Agencies developing such guidance will coordinate for consistency.

(e) Within 1 year of the date of this memorandum, the Department of the Interior will develop program guidance regarding the use of mitigation projects and measures on lands administered by bureaus or offices of the Department through a land-use authorization, cooperative agreement, or other appropriate mechanism that would authorize a project proponent to conduct actions, or otherwise secure conservation benefits, for the purpose of mitigating impacts elsewhere.

Sec. 5. *General Provisions*. (a) This memorandum complements and is not intended to supersede existing laws and policies.

(b) This memorandum shall be implemented consistent with applicable law, and subject to the availability of appropriations.

(c) This memorandum is intended for the internal guidance of the executive branch and is inapplicable to the litigation or settlement of natural resource damage claims. The provisions of section 3 this memorandum encouraging

restoration banking and advance restoration projects also do not apply to the selection or implementation of natural resource restoration plans, except to the extent determined appropriate in Federal trustee guidance developed pursuant to section 4(d) of this memorandum.

(d) The provisions of this memorandum shall not apply to military testing, training, and readiness activities.

(e) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(f) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(g) The Secretary of the Interior is hereby authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, November 3, 2015

[FR Doc. 2015–28466
Filed 11–5–15; 8:45 am]
Billing code 4310–10–P

Rules and Regulations

Federal Register
Vol. 80, No. 215
Friday, November 6, 2015

DEPARTMENT OF ENERGY

10 CFR Part 433

[Docket No. EERE–2014–BT–STD–0047]

RIN 1904–AD39

Energy Efficiency Standards for New Federal Commercial and Multi-Family High-Rise Residential Buildings' Baseline Standards Update

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (DOE) is publishing this final rule to implement provisions in the Energy Conservation and Production Act (ECPA) that require DOE to update the baseline Federal energy efficiency performance standards for the construction of new Federal commercial and multi-family high-rise residential buildings. This rule updates the baseline Federal commercial standard to the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 90.1–2013.

DATES: This rule is effective January 5, 2016.

The incorporation by reference of certain ANSI/ASHRAE/IES 90.1–2013 in this rule is approved by the Director of the Federal Register as of January 5, 2016.

All Federal agencies shall design new Federal buildings that are commercial and multi-family high-rise residential buildings, for which design for construction began on or after November 6, 2016, using ASHRAE Standard 90.1–2013 as the baseline standard for 10 CFR part 433.

ADDRESSES: This rulemaking can be identified by docket number EERE–2014–BT–STD–0047 and/or RIN number 1904–AD39.

Docket: The docket is available for review at *http://www.regulations.gov* including **Federal Register** Notices and other supporting documents/materials. All documents in the docket are listed in the *http://www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

FOR FURTHER INFORMATION CONTACT: For technical issues: Sarah Jensen, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Federal Energy Management Program, Mailstop EE–5F, 1000 Independence Avenue SW., Washington, DC 20585, (202) 287–6033, email: *sarah.jensen@ee.doe.gov.* For legal issues: Kavita Vaidyanathan, U.S. Department of Energy, Office of the General Counsel, Forrestal Building, GC–33, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–6609, email: *kavita.vaidyanathan@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

Material Under 1 CFR Part 51

This rulemaking incorporates by reference the following standard into 10 CFR part 433:

• ANSI/ASHRAE/IES Standard 90.1–2013, Energy Standard for Buildings Except Low-Rise Residential Buildings, I–P Edition, Copyright 2013.

Copies of this standard are available from the American Society of Heating Refrigerating and Air-Conditioning Engineers, Inc., 1791 Tullie Circle NE., Atlanta, GA 30329, (404) 636–8400, *http://www.ashrae.org.* The standard is discussed in greater detail in sections III and VI.N of this document.

Also, a copy of this standard is available for inspection at U.S. Department of Energy (DOE), Office of Energy Efficiency and Renewable Energy, Building Technologies Program, 6th Floor, 950 L'Enfant Plaza SW., Washington, DC 20024. For information on the availability of this standard at DOE, contact Ms. Brenda Edwards at (202) 586–2945 or email *Brenda.Edwards@ee.doe.gov.*

Table of Contents

I. Executive Summary of the Final Rule

Section 305 of the Energy Conservation and Production Act (ECPA), as amended, requires DOE to determine whether the energy efficiency standards for new Federal buildings should be updated to reflect revisions to ASHRAE Standard 90.1 based on the cost-effectiveness of the revisions. (42 U.S.C. 6834(a)(3)(B)) Accordingly, DOE conducted a cost-effectiveness analysis that found ASHRAE Standard 90.1–2013 to be cost-effective. DOE's assumptions and methodology for the cost-effectiveness of this rule are based on DOE's cost-effectiveness analysis of ASHRAE Standard 90.1–2013, as well as DOE's Environmental Assessment (EA) for this rulemaking.[1] Therefore, in this final rule, DOE updates the energy efficiency standards for new Federal buildings to ASHRAE Standard 90.1–2013 for buildings for which design for construction began on or after one year after the rule is published in the **Federal Register**. (42 U.S.C. 6834 (a)(3)(A)). Federal buildings are defined as follows: ''any building to be constructed by, or for the use of, any Federal agency. Such term shall include buildings built for the purpose of being leased by a Federal agency, and privatized military housing.'' (42 U.S.C. 6832 (6)). This term does not include renovations or modifications to existing buildings.

II. Introduction

ECPA, as amended, requires DOE to establish building energy efficiency standards for all new Federal buildings. (42 U.S.C. 6834(a)(1)) The standards established under section 305(a)(1) of ECPA must contain energy efficiency measures that are technologically feasible, economically justified, and meet the energy efficiency levels in the applicable voluntary consensus energy codes specified in section 305. (42 U.S.C. 6834(a)(1)–(3))

Under section 305 of ECPA, the referenced voluntary consensus code for commercial buildings (including multi-

[1] The Environmental Assessment (EA) (DOE/EA–2001) is entitled, ''Environmental Assessment for Final Rule, 10 CFR part 433, 'Energy Efficiency Standards for New Federal Commercial and Multi-Family High-Rise Residential Buildings,' Baseline Standards Update''. The EA and Finding Of No Significant Impact (FONSI) may be found in the docket for this rulemaking and at *http://energy.gov/node/984581.*

family high rise residential buildings) is the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 90.1. (42 U.S.C. 6834(a)(2)(A)) For the purposes of discussion in this preamble, all references to ''Federal buildings'' subject to 10 CFR 433 will include commercial and multi-family high-rise residential unless otherwise noted. DOE codified this referenced code as the baseline Federal building standard in its existing energy efficiency standards found in 10 CFR part 433. Also pursuant to section 305 of ECPA, DOE must establish, by rule, revised Federal building energy efficiency performance standards for new Federal buildings that require such buildings be designed to achieve energy consumption levels that are at least 30 percent below the levels established in the referenced code (baseline Federal building standard), if life-cycle cost-effective. (42 U.S.C. 6834(a)(3)(A)(i)(I))

Under section 305 of ECPA, not later than one year after the date of approval of each subsequent revision of the ASHRAE Standard or the International Energy Conservation Code (IECC), DOE must determine whether to amend the baseline Federal building standards with the revised voluntary standard based on the cost-effectiveness of the revised voluntary standard. (42 U.S.C. 6834(a)(3)(B)) It is this requirement that this rulemaking addresses. ASHRAE has updated Standard 90.1 from the version currently referenced in DOE's regulations at 10 CFR part 433. In this rule, DOE revises the latest baseline Federal building standard for 10 CFR part 433 from ASHRAE Standard 90.1–2010 to ASHRAE Standard 90.1–2013.

Section 306(a) of ECPA provides that each Federal agency and the Architect of the Capitol must adopt procedures to ensure that new Federal buildings will meet or exceed the Federal building energy efficiency standards established under section 305. (42 U.S.C. 6835(a)) ECPA Section 306(b) bars the head of a Federal agency from expending Federal funds for the construction of a new Federal building unless the building meets or exceeds the applicable baseline Federal building energy standards established under section 305. (42 U.S.C. 6835(b)) Specifically, all new Federal buildings must be designed to achieve the baseline standards in ASHRAE Standard 90.1 (and the International Energy Conservation Code for low-rise residential buildings) and achieve energy consumption levels at least 30 percent below these minimum baseline standards, where life-cycle cost-effective. (42 U.S.C. 6834 (a)(3)(A)). This requirement does not extend to renovations or modifications to existing buildings.

III. Discussion of the Final Rule

DOE is issuing this action as a final rule. As indicated above, DOE must determine whether the energy efficiency standards for new Federal buildings should be updated to reflect revisions to ASHRAE Standard 90.1 based on the cost-effectiveness of the revisions. (42 U.S.C. 6834(a)(3)(B)) In this final rule, DOE determines that the energy efficiency standards for new Federal buildings should be updated to reflect the 2013 revisions to ASHRAE Standard 90.1 based on the cost-effectiveness of the revisions.

DOE reviewed ASHRAE Standard 90.1 for DOE's state building codes program and determined that the 2013 version of ASHRAE Standard 90.1 would achieve greater energy efficiency than the prior version. (See 79 FR 57900 (Sept. 26, 2014)) This determination was subject to notice and comment. See 79 FR 27778 (May 15, 2014). In that determination, DOE found that the 2013 version of Standard 90.1 would save 8.5% more source energy than the 2010 version of Standard 90.1.

In DOE's determination for the state building codes program, and again in this rule, DOE states that the cost-effectiveness of revisions to the voluntary codes is considered through DOE's statutorily directed involvement in the codes process. See 79 FR 57900. Section 307 of ECPA requires DOE to participate in the ASHRAE code development process and to assist in determining the cost-effectiveness of the voluntary standards. (42 U.S.C. 6836) DOE is required to periodically review the economic basis of the voluntary building energy codes and participate in the industry process for review and modification, including seeking adoption of all technologically feasible and economically justified energy efficiency measures. (42 U.S.C. 6836(b))

In addition to DOE's consideration of the cost-effectiveness of ASHRAE 90.1–2013 through its participation in the codes development process, DOE conducted an independent analysis of the cost-effectiveness of ASHRAE Standard 90.1–2013. The results of the analysis are discussed below in section A. Review Under Executive Order 12866, ''Regulatory Planning and Review''.[2] DOE's assumptions and methodology for the cost-effectiveness of this rule are based on DOE's cost-effectiveness analysis of ASHRAE Standard 90.1–2013, as well as DOE's Environmental Assessment (EA) for this rulemaking.[3]

In this rule, DOE updates the energy efficiency standards applicable to new Federal buildings based on the determinations made by DOE as to the energy efficiency improvements of ASHRAE Standard 90.1–2013, as compared to the predecessor version, and based on the considerations of cost-effectiveness incorporated into the codes processes, DOE's involvement in those processes, and DOE's own cost-effectiveness analysis.[4] This final rule amends 10 CFR part 433 to update the referenced baseline Federal energy efficiency performance standards. No other changes are proposed to 10 CFR part 433 by this rule.

DOE also notes that there are a number of statutory provisions, regulations, Executive Orders, and memoranda of understanding that govern energy consumption in new Federal buildings. These include, but are not limited to, the Executive Order 13693 (80 FR 15871 (March 25, 2015)); sections 323, 433, 434, and 523 of EISA 2007; section 109 of the Energy Policy Act of 2005 (Pub. L. 109–58); and 10 CFR parts 433 and 435. This rule supports and does not supplant these other applicable legal requirements for new Federal buildings. For example, by designing buildings to meet the ASHRAE 90.1–2013 baseline, Federal agencies also help achieve the energy intensity reductions mandated under section 431 of EISA 2007.

Of particular significance is the Administration's Climate Action Plan, (CAP), issued June 2013, in which the President affirmed that the Federal government must position itself as a leader in clean energy and energy efficiency, and pledged that Federal agencies must surpass previous greenhouse gas reduction achievements, through a combination of consuming 20 percent of Federal electricity from renewable sources by 2020, and by pursuing greater energy efficiency in

[2] *National Cost-Effectiveness of ANSI/ASHRAE/IES Standard 90.1±2013,* Hart, R. *et. al.* PNNL–23834, Pacific Northwest National Laboratory, January 2015. *http://www.energycodes.gov/sites/default/files/documents/Cost-effectiveness_of_ASHRAE_Standard_90-1-2013-Report.pdf.*

[3] The Environmental Assessment (EA) (DOE/EA–2001) is entitled, ''Environmental Assessment for Final Rule, 10 CFR part 433, 'Energy Efficiency Standards for New Federal Commercial and Multi-Family High-Rise Residential Buildings,' Baseline Standards Update''. The EA and FONSI may be found in the docket for this rulemaking and at *http://energy.gov/node/984581.*

[4] Determination Regarding Energy Efficiency Improvements in ANSI/ASHRAE/IES Standard 90.1–2013: Energy Standard for Buildings, Except Low-Rise Residential Buildings; Notice of Determination September 26, 2014. *http://www.regulations.gov/#!documentDetail;D=EERE-2014-BT-DET-0009-0006.*

Federal buildings.[5] Additionally, the President directed that efficiency standards for appliances and federal buildings set in the first and second terms combined would reduce carbon pollution by at least 3 billion metric tons cumulatively by 2030—equivalent to nearly one-half of the carbon pollution from the entire U.S. energy sector for one year. Today's rule, which DOE estimates will avoid cumulative emissions of 6,234,000 metric tons of carbon dioxide through 2030, directly supports the Administration's undertaking to make energy efficiency in Federal buildings an essential stratagem in the government's enduring achievement of the greenhouse gas reduction goals set out in the CAP.

DOE further notes, on the subject of process loads, that the scope of building loads covered by ASHRAE Standard 90.1 broadened in ASHRAE Standard 90.1–2010 and again in ASHRAE Standard 90.1–2013 to cover ''new equipment or building systems specifically identified in the standard as part of an industrial or manufacturing process.'' [6] For example, Standard 90.1–2013 now includes escalator and moving walkway control requirements. Such requirements were not included in efficiency calculations under prior versions of ASHRAE Standard 90.1. Process loads are defined in 10 CFR 433.2 as ''the load on a building resulting from energy consumed in support of a manufacturing, industrial, or commercial process. Process loads do not include energy consumed maintaining comfort and amenities for the occupants of the building (including space conditioning for human comfort).'' Receptacle loads, also known as ''plug loads'' are defined in 10 CFR 433.2 as ''the load on a building resulting from energy consumed by any equipment plugged into electrical outlets.'' As in prior versions of the energy efficiency performance standards for new Federal commercial and multi-family high-rise residential buildings, DOE is maintaining the exclusion of process loads (for example, medical or industrial equipment) from the energy savings metric. Process loads typically involve specialized equipment for which improvements in energy efficiency may affect the functionality of the equipment or where improvements are not available at all. Some Federal buildings use most of their energy serving process loads, and application of the energy savings requirement to these buildings would likely place an undue burden on the rest of the building if the 30 percent savings is to be achieved.

In addition, DOE is also maintaining its exclusion of receptacle loads for the purpose of calculating energy savings under the Federal building standards because they are difficult to anticipate at the design stage and would change over time. (See 72 FR 72565, 72567–72568 (Dec. 21, 2007))

This rule clarifies that Federal agencies should continue to consider the building envelope and energy consuming systems normally specified as part of the building design covered by ASHRAE Standard 90.1 when determining if a design meets ASHRAE Standard 90.1 and whether achieving energy consumption levels at least 30% below the relevant ASHRAE baseline building is life-cycle cost-effective. Receptacle and process loads not explicitly covered in Standard 90.1, such as specialized medical or research equipment and equipment used in manufacturing processes, may be excluded from the calculations as noted in the rule.

IV. Compliance Date

This final rule applies to new Federal commercial and multi-family high-rise residential buildings for which design for construction begins on or after one year from the publication date of this rulemaking in the **Federal Register**. (42 U.S.C. 6834(a)(1)) Such buildings must be designed to exceed the energy efficiency level of the appropriate updated voluntary standard by 30 percent if life-cycle cost-effective. However, at a minimum, such buildings must achieve the energy efficiency equal to that of the appropriate updated voluntary standard. One year lead time before the design for construction begins is consistent with DOE's previous updates to the energy efficiency baselines and the original statutory mandate for Federal building standards. One year lead time before design for construction begins helps minimize compliance costs to agencies, which may have planned buildings in various stages of design, and allows for design changes to more fully consider life-cycle cost-effective measures (as opposed to having to revise designs in development, which may make incorporation of energy efficiency measure more difficult or expensive).

V. Reference Resources

The Department originally prepared this list of resources to help Federal agencies achieve building energy efficiency levels of at least 30 percent below ASHRAE Standard 90.1–2004. The Department has reviewed these resources and believes that they continue to be useful for helping agencies maximize their energy efficiency levels. The Department has updated this resource list as necessary. These resources come in many forms and in a variety of media. Resources are provided for all buildings, and also specifically for commercial and multi-family high-rise residential buildings.

Resources for Commercial and Multi-Family High-Rise Residential Buildings

1. Energy Efficient ProductsÐU.S. DOE Federal Energy Management Program and U.S. Environmental Protection Agency (EPA) ENERGY STAR Program

http://energy.gov/eere/femp/energy-and-water-efficient-products

Federal agencies are required by the Energy Policy Act of 2005 to specify Federal Energy Management Program (FEMP) designated or ENERGY STAR equipment, including building mechanical and lighting equipment and builder-supplied appliances, for purchase and installation in all new construction. This equipment is generally more efficient than the corresponding requirements of ASHRAE Standard 90.1–2013, and may be used to achieve part of the savings required of Federal building designs. (This rule does not specifically address the use of this equipment, but this Web site is listed for convenience because it is a very useful resource for achieving part of the energy savings required by the rule.)

2. Life-Cycle Cost AnalysisÐU.S. DOE Federal Energy Management Program

The life-cycle cost analysis rules promulgated in 10 CFR part 436 Subpart A *Life-Cycle Cost Methodology and Procedures* conform to requirements in the Federal Energy Management Improvement Act of 1988 (Pub. L. 100–615) and subsequent energy conservation legislation, as well as Executive Order 13693, *Planning for Federal Sustainability in the Next Decade.* The life-cycle cost guidance and required discount rates and energy price projections are determined annually by FEMP and the Energy Information Administration, and are published in the Annual Supplement to The National Institute of Standards and Technology Handbook 135: ''Energy Price Indices and Discount Factors for Life-Cycle Cost Analysis'' *http://www1.eere.energy.gov/femp/pdfs/ashb10.pdf.*

3. ENERGY STAR Target FinderÐU.S. Environmental Protection Agency and U.S. Department of Energy

http://www.energystar.gov/index.cfm?c=new_bldg_design.bus_target_finder

ENERGY STAR is a Government-backed program helping businesses and individuals

[5] The President's Climate Action Plan, Office of the Executive Office of the President, *https://www.whitehouse.gov/sites/default/files/image/president27sclimateactionplan.pdf,* June 2013.

[6] *See* section 2 in ASHRAE Standard 90.1–2013, ''Energy Standard for Buildings Except Low-Rise Residential Buildings, (I–P Edition)'' and section 2 in ''ASHRAE Standard 90.1–2010 ''Energy Standard for Buildings Except Low-Rise Residential Buildings, (I–P Edition)'' at: *http://www.ashrae.org.*

protect the environment through superior energy efficiency. The benchmarking tool and other information at the ENERGY STAR Target Finder Web site can be useful in determining an annual energy target for building design and computer simulations, evaluating cost-effectiveness of efficiency measures, and tracking a building's actual energy performance after construction.[7]

4. Building Energy Software ToolsÐU.S. DOE Building Technologies Program

http://apps1.eere.energy.gov/buildings/tools_directory/

This directory provides information on building software tools for evaluation energy efficiency, renewable energy, and sustainability in buildings.

5. ASHRAE Standard 90.1±2013ÐASHRAE

http://www.techstreet.com/ashrae/products/1865966

The baseline energy efficiency standard for commercial and multi-family high-rise buildings is ANSI/ASHRAE/IESNA Standard 90.1–2013. This link also contains a link to a read-only version of Standard 90.1–2013 under the Preview button.

6. Whole Building Design GuideÐNational Institute of Building Sciences

http://www.wbdg.org/

A portal providing one-stop access to up-to-date information on a wide range of building-related guidance, criteria and technology from a ''whole buildings'' perspective.

7. Labs for the 21st CenturyÐU.S. EPA and U.S. DOE

http://energy.gov/eere/femp/laboratories-21st-century

A Web site focused on improving the energy efficiency and environmental performance of laboratory space. This site includes training and educational resources and design tools focused on laboratories.

VI. Regulatory Analysis

A. Review Under Executive Order 12866, ``Regulatory Planning and Review''

This final rule is a ''significant regulatory action'' under Executive Order 12866, ''Regulatory Planning and Review.'' 58 FR 51735 (October 4, 1993). Accordingly, this action was subject to review by the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB). OMB has completed its review. As discussed previously in this rule, DOE is required to determine, based on the cost-effectiveness, whether the standards for Federal buildings should be updated to reflect an amendment to the ASHRAE standard. As stated above, DOE complied with the statutory language by analyzing the cost-effectiveness of ASHRAE Standard 90.1–2013, and through DOE's involvement in the ASHRAE code development process, including the consideration of ASHRAE's cost-effectiveness criteria for Standard 90.1–2013.[8]

DOE has also reviewed this regulation pursuant to Executive Order 13563, issued on January 18, 2011. 76 FR 3281 (January 21, 2011). EO 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866.

Review under Executive Order 12866 requires an analysis of the economic effect of the rule. For this purpose, DOE estimated incremental first cost (in this case, the difference between the cost of a building designed to meet ASHRAE Standard 90.1–2013 and a building designed to meet ASHRAE Standard 90.1–2010) for the Federal commercial and high-rise multi-family residential buildings sector, as well as life-cycle cost net savings. DOE determined that the total incremental first cost estimate is a savings of $1.2 million per year, with an average first cost decrease of $0.03 per square foot. DOE estimated $87.2 million in annual life-cycle cost (LCC) net savings for the entire Federal commercial and multi-family high-rise buildings sector with an average life-cycle cost net savings of $2.21 per square foot.

DOE's assumptions and methodology for the cost-effectiveness of this rule are based on DOE's cost-effectiveness analysis of ASHRAE Standard 90.1–2013, as well as DOE's Environmental Assessment (EA) for this rulemaking.[9] The EA identified a rate of new Federal commercial construction of 39.4 million square feet per year with a distribution of building types as shown in Table 1. As described in the EA, the distribution of building types is based on the 2007, 2008, 2009, 2010, and 2011 GSA Federal real property reports. Table 1 also shows the prototype buildings incorporated into computer simulations that are used to estimate energy use in each building type. DOE derived these prototype buildings from 16 building types in 17 climate zones [10] using its Commercial Prototype Building models.[11] Of the 16 prototype buildings, DOE developed costs for six prototype buildings to determine the cost effectiveness of ASHRAE Standard 90.1–2013. DOE then extracted the cost-effectiveness information for those prototype buildings and weighted those values as appropriate to obtain an average cost effectiveness value for building types found in the Federal commercial sector, as discussed in the EA.

TABLE 1—NEW FEDERAL COMMERCIAL AND HIGH-RISE MULTI-FAMILY CONSTRUCTION VOLUME BY BUILDING TYPE

Building type	Fraction of federal construction volume (by floor area)	Assumed prototypes
Office	0.63	Small Office,* Medium Office, Large Office.*
Education	0.083	Primary School,* Secondary School.
Dorm/Barracks	0.09	Small Hotel,* Large Hotel, Mid-Rise Apartment,* High-Rise Apartment.
Warehouse	0.15	Non-Refrigerated Warehouse.
Hospital	0.04	Outpatient Healthcare, Hospital.

* Indicates prototypes for which costs are available (See Table 2)

[7] The use of EPA's Target Finder tool during the design process of applicable new Federal buildings helps ensure that buildings are on a pathway to meet the existing building Federal Sustainable Building Guiding Principle (Energy Efficiency: Option 1), which is to receive an ENERGY STAR score of 75 or higher in EPA's Portfolio Manager.

[8] See *infra* at 1.

[9] The Environmental Assessment (EA) (DOE/EA–2001) is entitled, ''Environmental Assessment for Final Rule, 10 CFR part 433, 'Energy Efficiency Standards for New Federal Commercial and Multi-Family High-Rise Residential Buildings,' Baseline Standards Update''. The EA and FONSI may be found in the docket for this rulemaking and at *http://energy.gov/node/984581.*

[10] Briggs, R.S., R.G. Lucas, and Z.T. Taylor. 2003. ''Climate classification for building energy codes and standards: Part 1—Development Process.'' ASHRAE Transactions 109(1): 109:121. American Society of Heating, Refrigerating and Air-Conditioning Engineers. Atlanta, Georgia. The 90.1–2013 climate zone map may be viewed as Figure B.1 of the online version of Standard 90.1–2013 at *https://ashrae.iwrapper.com/ViewOnline/Standard_90.1-2013_I-P.*

[11] DOE's prototype buildings are described at *http://www.energycodes.gov/development/commercial/90.1_models.*

Notes:
1. Note that first cost data is not available for the prototypes assumed for warehouses and hospitals. As described below, DOE considered costs for the warehouse and hospital to be equivalent to the weighted cost for the offices, education, and dorm/barracks, which represents 81% of the Federal building stock.
2. DOE has preliminarily determined incremental cost and the life-cycle cost net savings information for the building types and climate zones analyzed. This information is shown in Tables 2 and 3.

TABLE 2—INCREMENTAL CONSTRUCTION FIRST COST (2013$) FOR ASHRAE 90.1–2013 VS. ASHRAE 90.1–2010

Prototype	Value	ASHRAE Climate zone				
		2A	3A	3B	4A	5A
Small Office	First Cost	($2,601)	($906)	($1,358)	$12,472	$9,072
	$/ft2	($0.47)	($0.16)	($0.25)	$2.27	$1.65
Large Office	First Cost	$352,647	($1,065,759)	($1,476,190)	$98,124	($1,014,770)
	$/ft2	$0.71	($2.14)	($2.96)	$0.20	($2.04)
Primary School	First Cost	$88,857	$119,646	$9,620	$167,916	$179,872
	$/ft2	$1.20	$1.62	$0.13	$2.27	$2.43
Small Hotel	First Cost	$20,483	$18,527	$18,675	$32,441	$39,120
	$/ft2	$0.47	$0.43	$0.43	$0.75	$0.91
Mid-rise Apartment	First Cost	$5,711	$23,214	$23,358	$12,891	$19,577
	$/ft2	$0.17	$0.69	$0.69	$0.38	$0.58

1. Notes: Negative costs (shown in parentheses) indicate a reduction in cost due to changes in the code, usually due to reduced HVAC capacity.[12]

DOE used data from Table 1 and Table 2 to calculate preliminary values for overall incremental first cost of construction for Federal commercial and high-rise, multi-family residential buildings. DOE calculated the incremental first cost of the Federal building types based on the DOE prototypes shown in bold font in Table 1. DOE then calculated the weighted average incremental cost for Federal building types based on the office, education, and dorm/barracks building types which represent an estimated 81% of new Federal construction. This weighted incremental cost was assigned to the warehouse and hospital building types and a total weighted incremental cost was calculated by multiplying the incremental cost for each Federal building type by the fraction of Federal construction shown in Table 1. For warehouses and hospitals DOE considered costs to be equivalent to the weighted cost for offices, education, and dorm/barracks.[13]

The national total incremental first cost for building types was developed by multiplying the average (across climate zones) incremental first cost of the prototypes (determined from the DOE ASHRAE Standard 90.1 cost-effectiveness analysis) by the fraction of the Federal sector construction volume shown in Table 1.[14] The resulting building type incremental first costs were then summed together to determine an overall incremental first cost for the entire Federal commercial and high-rise multi-family residential buildings sector. DOE estimates that total first cost outlays for new Federal buildings will be less under ASHRAE Standard 90.1 2013 than ASHRAE 90.1 2010, primarily due to cheaper equipment costs for some building types (See Table 2 and footnote 13 above). The resulting total incremental first cost estimate is a savings of $1.2 million per year. The average first cost decrease is $0.03 per square foot.

DOE also examined the relative impact of today's rule on the first cost of new constructed Federal buildings. Estimated construction costs for new Federal commercial and high-rise multifamily buildings were obtained from RS Means (2014)[15] for the 5 buildings types analyzed in DOE's cost-effectiveness methodology plus two additional building types that are reasonably common in the Federal sector—hospitals and warehouses. Weights for the Federal building types and relationships between Federal building types and the DOE prototypes used in the cost-effectiveness analysis are shown in Table 1. The results of this analysis are shown in Table 3. For the assumptions used in this rulemaking, the average cost of a new Federal building would be $135 per square foot. This cost may be multiplied by the 39.4 million square feet of new Federal construction per year used in this rulemaking to estimate the total cost of new Federal commercial and high-rise multi-family construction at $5.325 billion. Savings associated with this rulemaking are estimated at $1.2 million per year, indicating a potential cost reduction in new Federal construction costs of 0.023%.

TABLE 3—FIRST COST OF TYPICAL NEW FEDERAL BUILDING IN $/FT2

BECP Prototype	Building first cost $/ft2	Corresponds to Federal building type	Federal weighting (%)	Weighted cost ($)
Small Office	132	Small Office	32	42
Large Office	166	Large Office	32	52

[12] In this particular transition from 90.1–2010 to 90.1–2013, the cost reduction was mainly because of smaller and less expensive HVAC equipment since the building load had decreased. This cost reduction is part of the first cost calculation. Note that in addition to reduced equipment costs, there is reduced ductwork or piping costs as well.

[13] There are no data for those years for warehouses or hospitals. It could be expected that costs to a warehouse would be less since it is a simpler building. We assumed both the warehouse and the hospital were the ''average'' of the data we did have. And so, the warehouse value is likely higher than it might have been and the hospital value is likely lower than it might have been had there been data available.

[14] For the Federal office building, the small and large office prototype first costs were averaged. For the Federal education building, the primary school prototype first cost was used. For the Federal dorm/barracks building type, the small hotel and mid-rise apartment prototype first costs were averaged.

[15] RS Means. 2014. RS Means Building Construction Cost Data, 72nd Ed. Construction Publishers & Consultants. Norwell, MA.

TABLE 3—FIRST COST OF TYPICAL NEW FEDERAL BUILDING IN $/FT²—Continued

BECP Prototype	Building first cost $/ft²	Corresponds to Federal building type	Federal weighting (%)	Weighted cost ($)
Primary School	138	Education	8	11
Small Hotel	111	Barracks/Dormitory	5	5
Mid-Rise Apartment	117	Barracks/Dormitory	5	5
Hospital	253	Hospital	4	10
Warehouse	63	Warehouse	15	9
Total			99	135

Turning to LCC net savings, DOE estimated the LCC net savings to be $87.2 million for 39.4 million square feet of annual construction, with the average life-cycle cost net savings in year one estimated at $2.21 per square foot. Table 4 shows annual LCC net savings by prototype buildings. For LCC net savings, DOE used a similar approach to that used for incremental first cost. That is, DOE developed the national total annual LCC net savings [16] for building types by multiplying the average (across climate zones) LCC net savings (determined from the DOE ASHRAE 90.1 cost-effectiveness analysis) by the fraction of the federal sector construction volume shown in Table 1.[17] The results of the building type LCC net savings were then summed together to determine the overall annual LCC net savings for the entire Federal commercial and high-rise multi-family buildings sector. The resulting total LCC net savings for 39.4 million square feet of annual construction was estimated to be $87.2 million. The average life-cycle cost net savings in year one was estimated to be $2.21 per square foot. Note the annual LCC savings are for one year of Federal commercial and high-rise multi-family residential construction and that those savings would accumulate over the LCC evaluation period. For the purpose of this analysis, DOE relied on a 30-year period.[18]

TABLE 4—ANNUAL LIFE-CYCLE COST (LCC) NET SAVINGS (2013$) FOR ASHRAE 90.1–2013 VS. ASHRAE 90.1–2010

Prototype		ASHRAE Climate zone				
	Value	2A	3A	3B	4A	5A
Small Office	Total	$21,600.00	$15,200.00	$10,800.00	$2,900.00	$5,000.00
	$/ft²	3.93	2.76	1.96	0.51	0.91
Large Office	Total	740,000.00	1,650,000.00	2,540,000.00	310,000.00	1,340,000.00
	$/ft²	1.48	3.31	5.09	0.60	2.69
Primary School	Total	246,000.00	116,000.00	398,000.00	70,000.00	109,000.00
	$/ft²	3.33	1.57	5.38	0.95	1.47
Small Hotel	Total	96,410.00	76,000.00	78,000.00	62,600.00	68,000.00
	$/ft²	2.23	1.76	1.81	1.45	1.57
Mid-rise Apartment	Total	59,600.00	22,600.00	23,800.00	29,200.00	28,500.00
	$/ft²	1.77	0.67	0.71	0.87	0.84

B. Administrative Procedure Act

DOE notes that the determination regarding ASHRAE Standard 90.1–2013 in the context of State building codes was subject to notice and comment in evaluating the voluntary consensus codes. See 76 FR 43298 (July 20, 2011) for the preliminary determination and 76 FR 64904 (October 19, 2011) for the final determination. The determinations made in the context of the State codes are equally applicable in the context of Federal buildings. DOE finds that providing notice and comment on the determinations again in the context of Federal buildings would be unnecessary. The fact that the voluntary consensus codes apply to Federal buildings as opposed to the general building stock does not require a different evaluation of energy efficiency and cost-effectiveness. Additionally, DOE notes that this rule, which updates energy efficiency performance standards for the design and construction of new Federal buildings, is a rule relating to public property, and therefore is not subject to the rulemaking requirements of the Administrative Procedure Act, including the requirement to publish a notice of proposed rulemaking. (See 5 U.S.C. 553(a)(2))

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires the preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, *Proper Consideration of Small Entities in Agency Rulemaking,* 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19,

[16] The energy costs used were the national average energy costs used by ASHRAE in the development of Standard 90.1–2013. To quote the cost-effectiveness analysis report ''Energy rates used to calculate the energy costs from the modeled energy usage were $0.990/therm for fossil fuel and $0.1032/kWh for electricity. These rates were used for the 90.1–2013 energy analysis, and derived from the US DOE Energy Information Administration data. These were the values approved by 90.1–2013''.

[17] For the Federal office building, the small and large office prototype life cycle costs were averaged. For the Federal education building, the primary school prototype life cycle cost was used. For the Federal dorm/barracks building type, the small hotel and mid-rise apartment prototype life cycle costs were averaged.

[18] Rushing, A, J Kneifel, and B Lippiatt. 2013. Energy Price Indices and Discount Factors for Life-Cycle Cost Analysis-2013: Annual Supplement to NIST Handbook 135 and NBS Special Publication 709.

2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process, 68 FR 7990. The Department has made its procedures and policies available on the Office of General Counsel's Web site: *http://energy.gov/gc/office-general-counsel.*

DOE has determined that a notice of proposed rulemaking is not required by 5 U.S.C. 553 or any other law for issuance of this rule. As such, the analytical requirements of the Regulatory Flexibility Act do not apply.

D. Review Under the Paperwork Reduction Act of 1995

This rulemaking will impose no new information or record keeping requirements. Accordingly, Office of Management and Budget (OMB) clearance is not required under the Paperwork Reduction Act. (44 U.S.C. 3501 *et seq*).

E. Review Under the National Environmental Policy Act of 1969

The Department prepared an Environmental Assessment (EA) (DOE/EA–2001) entitled, ''Environmental Assessment for Final Rule, 10 CFR part 433, 'Energy Efficiency Standards for New Federal Commercial and Multi-Family High-Rise Residential Buildings,' Baseline Standards Update,'' [19] pursuant to the Council on Environmental Quality's (CEQ) Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act (40 CFR parts 1500–1508), the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), and DOE's NEPA Implementing Procedures (10 CFR part 1021).

The EA addresses the possible incremental environmental effects attributable to the application of the final rule. The only anticipated impact would be a decrease in outdoor air pollutants resulting from decreased fossil fuel burning for energy use in Federal buildings. Therefore, DOE has issued a Finding of No Significant Impact (FONSI), pursuant to NEPA, the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and DOE's regulations for compliance with NEPA (10 CFR part 1021).

To identify the potential environmental impacts that may result from implementing the final rule on new Federal commercial buildings, DOE compared the requirements of the final rule updating energy efficiency performance standard for Federal new commercial and multi-family high rise residential buildings to ASHRAE Standard 90.1–2013 with the ''no-action alternative'' of using the current Federal standards (ASHRAE Standard 90.1–2010). This comparison is identical to that undertaken by DOE in its determinations of energy savings of those standards and codes.

Accordingly, DOE concludes in the EA that new Federal buildings designed and constructed to Standard 90.1–2013 will use less energy than new Federal buildings designed and constructed to Standard 90.1–2010 because Standard 90.1–2013 is more efficient than Standard 90.1–2010. This decrease in energy usage translates to reduced emissions of carbon dioxide (CO_2), nitrogen oxides (NO_X), and mercury (Hg) over the thirty-year period examined in the EA. Cumulative emission reductions for 30 years of construction (2015 through 2044) and 30 years of energy reduction for each building built during that period can be estimated at up to 24,156,900 metric tons of CO_2, up to 24,564 metric tons of NO_X, and up to 0.3357 metric tons of Hg. DOE conducted a separate calculation to determine emissions reductions relative to the targets identified in the CAP. This calculation showed that the cumulative reduction in CO_2 emissions through 2030 amounts to 6,234,000 metric tons of CO_2.[20]

F. Review Under Executive Order 13132, ``Federalism''

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations, 65 FR 13735. DOE examined this rule and determined that it does not preempt State law and does not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of Government. No further action is required by Executive Order 13132.

G. Review Under Executive Order 12988, ``Civil Justice Reform''

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (February 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct, rather than a general standard and promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this rule meets the relevant standards of Executive Order 12988.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and tribal governments and the private sector. For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written

[19] The EA and FONSI may be found in the docket for this rulemaking and at *http://energy.gov/node/984581.*

[20] See discussion of CAP calculations in footnote 12 on page 23 of the EA for this rule. The EA and FONSI may be found in the docket for this rulemaking and at *http://energy.gov/node/984581.*

statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a) and (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and tribal governments on a proposed ''significant intergovernmental mandate'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA (62 FR 12820) (also available at *http://energy.gov/gc/office-general-counsel*). This final rule contains neither an intergovernmental mandate nor a mandate that may result in the expenditure of $100 million or more in any year by State, local, and tribal governments, in the aggregate, or by the private sector, so these requirements under the Unfunded Mandates Reform Act do not apply.

I. Review Under the Treasury and General Government Appropriations Act of 1999

Section 654 of the Treasury and General Government Appropriations Act of 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This final rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under Executive Order 12630, ``Governmental Actions and Interference With Constitutionally Protected Property Rights''

The Department has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights'' 53 FR 8859 (March 18, 1988) that this rule would not result in any takings which might require compensation under the Fifth Amendment to the United States Constitution.

K. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed today's final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

L. Review Under Executive Order 13211, ``Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use''

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. DOE's Energy Information Administration (EIA) estimates that new construction in the commercial sector will range from 1.7 billion square feet per year in 2015 to 2.4 billion square feet per year in 2040.[21] This rule is expected to incrementally reduce the energy usage of approximately 39.4 million square feet of Federal commercial and high-rise multi-family residential construction annually.[22] Thus, the rule represents approximately 2.3% of the expected annual US construction in 2015, falling to approximately 1.6% in the year 2040. This final rule would not have a significant adverse effect on the supply, distribution, or use of energy and, therefore, is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

M. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91), DOE must comply with section 32 of the Federal Energy Administration Act of 1974 (Pub. L. 93–275), as amended by the Federal Energy Administration Authorization Act of 1977 (Pub. L. 95–70). (15 U.S.C. 788) Section 32 provides that where a proposed rule authorizes or requires use of commercial standards, the NOPR must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Department of Justice (DOJ) and the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition.

Although section 32 specifically refers to the proposed rule stage, DOE is meeting these requirements at the final rule stage because there was no proposed rule for this action. This final rule incorporates testing methods contained in the following commercial standard: ANSI/ASHRAE/IES Standard 90.1–2013, Energy Standard for Buildings Except Low-Rise Residential Buildings, 2013, American Society of Heating Refrigerating and Air-Conditioning Engineers, Inc., ISSN 1041–2336.

DOE has evaluated these standards and notes that the ASHRAE 90.1 Standard is developed under American National Standards Institute (ANSI)-approved consensus procedures, and is under continuous maintenance by a Standing Standard Project Committee. ASHRAE has established a program for regular publication of addenda, or revisions, including procedures for timely, documented, consensus action on requested changes to the ASHRAE 90.1 Standard. ANSI approved the final addendum for inclusion in the 2013 edition in September 2013. Standard 90.1–2013 was published in October 2013. However, DOE is unable to conclude whether ASHRAE Standard 90.1 fully complies with the requirements of section 32(b) of the FEAA (*i.e.* whether they were developed in a manner that fully provides for public participation, comment, and review). DOE has consulted with both the Attorney General and the Chairman

[21] See Table A5 of the 2015 Annual Energy Outlook (beta) at *http://www.eia.gov/beta/aeo/#/?id=5-AEO2015* or Table A5 of the 2014 Annual Energy Outlook at *http://www.eia.gov/oiaf/aeo/tablebrowser/#release=AEO2014&subject=0-AEO2014&table=5-AEO2014&region=0-0&cases=full2013full-d102312a,ref2014-d102413a.*

[22] See Regulatory Analysis Section A. Review Under Executive Order 12866, ''Regulatory Planning and Review'' above for origin of the 39.4 million square foot estimate.

of the FTC about the impact on competition of using the methods contained in these standards and has received no comments objecting to their use.

N. Description of Materials Incorporated by Reference

In this rule, DOE incorporates by reference ANSI/ASHRAE/IES Standard 90.1–2013, Energy Standard for Buildings Except Low-Rise Residential Buildings, (I–P Edition), Copyright 2013. This U.S. standard provides minimum requirements for energy efficient designs for buildings except for low-rise residential buildings. Copies of this standard are available from the American Society of Heating Refrigerating and Air-Conditioning Engineers, Inc., 1791 Tullie Circle NE., Atlanta, GA 30329, (404) 636–8400, *http://www.ashrae.org.*

VII. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

VIII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 433

Buildings and facilities, Energy conservation, Engineers, Federal buildings and facilities, Housing, Incorporation by reference.

Issued in Washington, DC, on October 23, 2015.

David Danielson,

Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, the Department of Energy amends chapter II of title 10 of the Code of Federal Regulations as set forth below:

PART 433—ENERGY EFFICIENCY STANDARDS FOR DESIGN AND CONSTRUCTION OF NEW FEDERAL COMMERCIAL AND MULTI FAMILY HIGH RISE RESIDENTIAL BUILDINGS

■ 1. The authority citation for part 433 continues to read as follows:

Authority: 42 U.S.C. 6831–6832; 6834–6835; 42 U.S.C. 7101 *et seq.*

■ 2. Amend § 433.2 by adding in alphabetical order the definition of ''ASHRAE Baseline Building 2013'' to read as follows:

§ 433.2 Definitions.

* * * * *

ASHRAE Baseline Building 2013 means a building that is otherwise identical to the proposed building but is designed to meet, but not exceed, the energy efficiency specifications in ANSI/ASHRAE/IES Standard 90.1–2013, Energy Standard for Buildings Except Low-Rise Residential Buildings, 2013 (incorporated by reference, see § 433.3).

* * * * *

■ 3. Amend § 433.3 by adding paragraph (b)(4) to read as follows:

§ 433.3 Materials incorporated by reference.

* * * * *

(b) * * *

(4) ANSI/ASHRAE/IES 90.1–2013, (''ASHRAE 90.1–2013''), Energy Standard for Buildings Except Low-Rise Residential Buildings, I–P Edition, Copyright 2013, IBR approved for §§ 433.2, 433.100, and 433.101.

■ 4. Amend § 433.100 by:

■ a. Revising the introductory text of paragraphs (a)(2) and (3);

■ b. Adding paragraph (a)(4); and

■ c. Revising paragraph (b).

The revisions and addition read as follows:

§ 433.100 Energy efficiency performance standard.

(a) * * *

(2) All Federal agencies shall design new Federal buildings that are commercial and multi-family high-rise residential buildings, for which design for construction began on or after August 10, 2012, but before July 9, 2014, to:

* * * * *

(3) All Federal agencies shall design new Federal buildings that are commercial and multi-family high-rise residential buildings, for which design for construction began on or after July 9, 2014, but before November 6, 2016 to:

* * * * *

(4) All Federal agencies shall design new Federal buildings that are commercial and multi-family high-rise residential buildings, for which design for construction began on or after November 6, 2016 to:

(i) Meet ASHRAE 90.1–2013, (incorporated by reference, see § 433.3); and

(ii) If life-cycle cost-effective, achieve energy consumption levels, calculated consistent with paragraph (b) of this section, that are at least 30 percent below the levels of the ASHRAE Baseline Building 2013.

(b) Energy consumption for the purposes of calculating the 30 percent savings requirements shall include the building envelope and energy consuming systems normally specified as part of the building design by ASHRAE 90.1 such as space heating, space cooling, ventilation, service water heating, and lighting, but shall not include receptacle and process loads not within the scope of ASHRAE 90.1 such as specialized medical or research equipment and equipment used in manufacturing processes.

* * * * *

■ 5. Amend § 433.101 by:

■ a. Revising the introductory text of paragraphs (a)(2) and (a)(3);

■ b. Adding paragraph (a)(4); and

■ c. Revising paragraph (b).

The revisions and addition read as follows:

§ 433.101 Performance level determination.

(a) * * *

(2) For Federal buildings for which design for construction began on or after August 10, 2012, but before July 9, 2014, each Federal agency shall determine energy consumption levels for both the ASHRAE Baseline Building 2007 and proposed building by using the Performance Rating Method found in Appendix G of ASHRAE 90.1–2007 (incorporated by reference, see § 433.3), except the formula for calculating the Performance Rating in paragraph G1.2 shall read as follows:

* * * * *

(3) For Federal buildings for which design for construction began on or after July 9, 2014, but before November 6, 2016 each Federal agency shall determine energy consumption levels for both the ASHRAE Baseline Building 2010 and proposed building by using the Performance Rating Method found in Appendix G of ASHRAE 90.1–2010 (incorporated by reference, see § 433.3), except the formula for calculating the Performance Rating in paragraph G1.2 shall read as follows:

* * * * *

(4) For Federal buildings for which design for construction began on or after before November 6, 2016 each Federal agency shall determine energy consumption levels for both the ASHRAE Baseline Building 2013 and proposed building by using the Performance Rating Method found in Appendix G of ASHRAE 90.1–2013 (incorporated by reference, see § 433.3), except the formula for calculating the Performance Rating in paragraph G1.2 shall read as follows:

(i) Percentage improvement = 100 × ((Baseline building consumption − Receptacle and process

loads) − (Proposed building consumption − Receptacle and process loads))/(Baseline building consumption − Receptacle and process loads) (which simplifies as follows):

(ii) Percentage improvement = 100 × (Baseline building consumption − Proposed building consumption)/(Baseline building consumption − Receptacle and process loads).

(b) Energy consumption for the purposes of calculating the 30 percent savings requirements in § 433.100 shall include the building envelope and energy consuming systems normally specified as part of the building design by ASHRAE 90.1 such as space heating, space cooling, ventilation, service water heating, and lighting, but shall not include receptacle and process loads not within the scope of ASHRAE 90.1 such as specialized medical or research equipment and equipment used in manufacturing processes.

[FR Doc. 2015–28078 Filed 11–5–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31042; Amdt. No. 3665]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective November 6, 2015. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 6, 2015.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE., West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Richard A. Dunham III, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125), Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part § 97.20. The applicable FAA forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFRs and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and

contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26,1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC on October 9, 2015.

John Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 12 NOVEMBER 2015

Auburn, IN, De Kalb County, VOR–A, Amdt 10
North Adams, MA, Harriman-And-West, Takeoff Minimums and Obstacle DP, Orig
Sidney, OH, Sidney Muni, RNAV (GPS) RWY 10, Amdt 1
Sidney, OH, Sidney Muni, RNAV (GPS) RWY 28, Amdt 1
Sidney, OH, Sidney Muni, VOR–A, Orig
Sidney, OH, Sidney Muni, VOR OR GPS RWY 23, Amdt 12B, CANCELED

Effective 10 DECEMBER 2015

Bakersfield, CA, Meadows Field, ILS OR LOC RWY 30R, Amdt 31
Bakersfield, CA, Meadows Field, RNAV (GPS) RWY 30R, Amdt 2
Monterey, CA, Monterey Rgnl, GPS RWY 28R, Orig-A, CANCELED
Monterey, CA, Monterey Rgnl, ILS OR LOC RWY 10R, Amdt 28
Monterey, CA, Monterey Rgnl, RNAV (GPS) RWY 10L, Orig, CANCELED
Monterey, CA, Monterey Rgnl, RNAV (GPS) RWY 10R, Amdt 1
Monterey, CA, Monterey Rgnl, RNAV (GPS) Y RWY 10R, Orig, CANCELED
Oakland, CA, Metropolitan Oakland Intl, ILS OR LOC/DME RWY 28R, Amdt 37
Oakland, CA, Metropolitan Oakland Intl, RNAV (GPS) Y RWY 28R, Amdt 3
Oakland, CA, Metropolitan Oakland Intl, RNAV (RNP) Z RWY 28R, Amdt 2
Delta, CO, Blake Field, RNAV (GPS) RWY 3, Orig
Delta, CO, Blake Field, Takeoff Minimums and Obstacle DP, Orig
Dodge City, KS, Dodge City Rgnl, RNAV (GPS) RWY 14, Amdt 1A
Dodge City, KS, Dodge City Rgnl, RNAV (GPS) RWY 32, Amdt 2
Enid, OK, Enid Woodring Rgnl, RNAV (GPS) RWY 35, Amdt 1
Enid, OK, Enid Woodring Rgnl, Takeoff Minimums and Obstacle DP, Amdt 4
Enid, OK, Enid Woodring Rgnl, VOR RWY 35, Amdt 15
Humboldt, TN, Humboldt Muni, RNAV (GPS) RWY 4, Orig
Humboldt, TN, Humboldt Muni, RNAV (GPS) RWY 22, Orig
Humboldt, TN, Humboldt Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Humboldt, TN, Humboldt Muni, VOR/DME–A, Amdt 5A, CANCELED
Fort Worth, TX, Fort Worth Alliance, RNAV (GPS) RWY 16R, Orig
Salt Lake City, UT, Salt Lake City Intl, ILS OR LOC RWY 17, ILS RWY 17 (SA CAT I), ILS RWY 17 (SA CAT II), Amdt 14
Salt Lake City, UT, Salt Lake City Intl, RNAV (GPS) RWY 17, Amdt 2

[FR Doc. 2015–28117 Filed 11–5–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31043; Amdt. No. 3666]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective November 6, 2015. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 6, 2015.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE., West Bldg., Ground Floor, Washington, DC, 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Richard A. Dunham III, Flight Procedure Standards Branch (AFS–420) Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK. 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary.

This amendment provides the affected CFRs, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC on October 9, 2015.

John Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [AMENDED]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
12–Nov–15 ...	AZ	Globe	San Carlos Apache	5/0529	09/30/15	GPS RWY 27, Orig-A.
12–Nov–15 ...	FL	Brooksville	Brooksville-Tampa Bay Rgnl ...	5/0653	09/30/15	RNAV (GPS) RWY 3, Amdt 1C.
12–Nov–15 ...	CA	Marysville	Yuba County	5/0918	09/29/15	RNAV (GPS) RWY 14, Orig-C.
12–Nov–15 ...	MN	Mankato	Mankato Rgnl	5/0985	10/06/15	COPTER ILS OR LOC RWY 33, Orig-B.
12–Nov–15 ...	ND	Harvey	Harvey Muni	5/2418	09/29/15	RNAV (GPS) RWY 29, Orig-A.
12–Nov–15 ...	CO	Craig	Craig-Moffat	5/2420	09/29/15	VOR/DME RWY 7, Amdt 2B.
12–Nov–15 ...	MI	Charlotte	Fitch H Beach	5/2421	09/29/15	RNAV (GPS) RWY 20, Orig.
12–Nov–15 ...	MI	Charlotte	Fitch H Beach	5/2422	09/29/15	VOR RWY 20, Amdt 11.
12–Nov–15 ...	AR	Batesville	Batesville Rgnl	5/2705	09/29/15	RNAV (GPS) RWY 26, Amdt 1.
12–Nov–15 ...	AR	Batesville	Batesville Rgnl	5/2706	09/29/15	LOC RWY 8, Amdt 1.
12–Nov–15 ...	AR	Batesville	Batesville Rgnl	5/2707	09/29/15	RNAV (GPS) RWY 8, Amdt 1A.
12–Nov–15 ...	IA	Harlan	Harlan Muni	5/2965	09/29/15	GPS RWY 15, Orig-A.
12–Nov–15 ...	IA	Harlan	Harlan Muni	5/2966	09/29/15	GPS RWY 33, Orig-A.
12–Nov–15 ...	KS	Hill City	Hill City Muni	5/3297	09/30/15	RNAV (GPS) RWY 18, Amdt 1A.
12–Nov–15 ...	TN	Winchester	Winchester Muni	5/3334	09/22/15	RNAV (GPS) Y RWY 18, Orig-A.
12–Nov–15 ...	TN	Winchester	Winchester Muni	5/3335	09/22/15	NDB RWY 18, Amdt 6A.
12–Nov–15 ...	TN	Winchester	Winchester Muni	5/3336	09/22/15	RNAV (GPS) Z RWY 18, Orig-A.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
12–Nov–15 ...	TN	Winchester	Winchester Muni	5/3337	09/22/15	RNAV (GPS) RWY 36, Orig-A.
12–Nov–15 ...	NY	Farmingdale	Republic	5/3360	09/22/15	NDB RWY 1, Amdt 14B.
12–Nov–15 ...	NY	Farmingdale	Republic	5/3361	09/22/15	RNAV (GPS) RWY 19, Amdt 2C.
12–Nov–15 ...	NY	Farmingdale	Republic	5/3362	09/22/15	RNAV (GPS) RWY 1, Amdt 2B.
12–Nov–15 ...	TN	Rockwood	Rockwood Muni	5/3505	09/22/15	RNAV (GPS) RWY 22, Amdt 1.
12–Nov–15 ...	TN	Rockwood	Rockwood Muni	5/3508	09/22/15	RNAV (GPS) RWY 4, Orig.
12–Nov–15 ...	WI	Waukesha	Waukesha County	5/6258	09/29/15	RNAV (GPS) RWY 10, Orig.
12–Nov–15 ...	NE	Ord	Evelyn Sharp Field	5/6260	09/29/15	RNAV (GPS) RWY 13, Orig-A.
12–Nov–15 ...	MO	Cassville	Cassville Muni	5/6261	09/29/15	VOR RWY 9, Amdt 2.
12–Nov–15 ...	TX	Center	Center Muni	5/6276	09/29/15	RNAV (GPS) RWY 35, Orig.
12–Nov–15 ...	TX	Center	Center Muni	5/6277	09/29/15	RNAV (GPS) RWY 17, Orig-A.
12–Nov–15 ...	OH	Youngstown/Warren	Youngstown-Warren Rgnl	5/6278	09/29/15	ILS OR LOC RWY 14, Amdt 8A.
12–Nov–15 ...	OH	Youngstown/Warren	Youngstown-Warren Rgnl	5/6279	09/29/15	ILS OR LOC RWY 32, Amdt 27A.
12–Nov–15 ...	OH	Youngstown/Warren	Youngstown-Warren Rgnl	5/6280	09/29/15	NDB RWY 32, Amdt 20A.
12–Nov–15 ...	OH	Youngstown/Warren	Youngstown-Warren Rgnl	5/6282	09/29/15	RADAR 1, Amdt 13A.
12–Nov–15 ...	OH	Youngstown/Warren	Youngstown-Warren Rgnl	5/6283	09/29/15	RNAV (GPS) RWY 14, Orig.
12–Nov–15 ...	OH	Youngstown/Warren	Youngstown-Warren Rgnl	5/6284	09/29/15	RNAV (GPS) RWY 32, Orig-B.
12–Nov–15 ...	OH	Youngstown/Warren	Youngstown-Warren Rgnl	5/6285	09/29/15	VOR–A, Orig.
12–Nov–15 ...	ID	Coeur D'Alene	Coeur D'Alene-Pappy Boyington Field.	5/6537	09/29/15	VOR/DME RWY 2, Amdt 2B.
12–Nov–15 ...	ID	Coeur D'Alene	Coeur D'Alene-Pappy Boyington Field.	5/6538	09/29/15	ILS OR LOC/DME RWY 6, Amdt 5C.
12–Nov–15 ...	ID	Coeur D'Alene	Coeur D'Alene-Pappy Boyington Field.	5/6540	09/29/15	RNAV (GPS) RWY 6, Orig-C.
12–Nov–15 ...	ID	Coeur D'Alene	Coeur D'Alene-Pappy Boyington Field.	5/6541	09/29/15	VOR RWY 6, Orig-C.
12–Nov–15 ...	ID	Coeur D'Alene	Coeur D'Alene-Pappy Boyington Field.	5/6542	09/29/15	NDB RWY 6, Amdt 2D.
12–Nov–15 ...	WA	Bremerton	Bremerton National	5/6569	09/29/15	Takeoff Minimums and (Obstacle) DP, Amdt 5.
12–Nov–15 ...	CA	San Diego	San Diego Intl	5/6675	09/29/15	RNAV (GPS) RWY 27, Amdt 3C.
12–Nov–15 ...	MO	Springfield	Springfield-Branson National ..	5/6815	09/29/15	RNAV (GPS) RWY 32, Amdt 2A.
12–Nov–15 ...	TX	Mount Vernon	Franklin County	5/6817	09/29/15	RNAV (GPS) RWY 13, Orig.
12–Nov–15 ...	TX	Mount Vernon	Franklin County	5/6818	09/29/15	RNAV (GPS) RWY 31, Orig.
12–Nov–15 ...	CA	Truckee	Truckee-Tahoe	5/7132	09/29/15	RNAV (GPS) Y RWY 20, Orig-A.
12–Nov–15 ...	CA	Truckee	Truckee-Tahoe	5/7133	09/29/15	RNAV (GPS) Z RWY 20, Orig-B.
12–Nov–15 ...	CA	Truckee	Truckee-Tahoe	5/7134	09/29/15	RNAV (GPS) RWY 11, Orig-A.
12–Nov–15 ...	MN	Mankato	Mankato Rgnl	5/7267	09/22/15	ILS RWY 33, Amdt 1.
12–Nov–15 ...	PA	Altoona	Altoona-Blair County	5/7687	09/30/15	ILS OR LOC RWY 21, Amdt 8.
12–Nov–15 ...	PA	Altoona	Altoona-Blair County	5/7688	09/30/15	RNAV (GPS) RWY 21, Amdt 1A.
12–Nov–15 ...	IN	Auburn	De Kalb County	5/7736	09/30/15	VOR RWY 9, Amdt 7C.
12–Nov–15 ...	IN	Auburn	De Kalb County	5/7737	09/30/15	RNAV (GPS) RWY 9, Orig-B.
12–Nov–15 ...	IN	Auburn	De Kalb County	5/7738	09/30/15	ILS OR LOC RWY 27, Amdt 1B.
12–Nov–15 ...	IN	Auburn	De Kalb County	5/7739	09/30/15	RNAV (GPS) RWY 27, Orig-B.
12–Nov–15 ...	CA	Marysville	Yuba County	5/7760	09/29/15	ILS OR LOC RWY 14, Amdt 5D.
12–Nov–15 ...	CA	Marysville	Yuba County	5/7761	09/29/15	VOR RWY 32, Amdt 10G.
12–Nov–15 ...	CA	Marysville	Yuba County	5/7763	09/29/15	RNAV (GPS) RWY 32, Orig-C.
12–Nov–15 ...	IL	Peoria	General Downing-Peoria Intl ...	5/8231	09/29/15	VOR OR TACAN RWY 13, Amdt 23B.
12–Nov–15 ...	OR	Portland	Portland Intl	5/9949	09/29/15	ILS OR LOC RWY 10L, Amdt 4A.

[FR Doc. 2015–28118 Filed 11–5–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31044; Amdt. No. 3667]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight

operations under instrument flight rules at the affected airports.

DATES: This rule is effective November 6, 2015. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 6, 2015.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE., West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Richard A. Dunham III, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125), Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part § 97.20. The applicable FAA forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on October 23, 2015.

John Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 10 DECEMBER 2015

Atqasuk, AK, Atqasuk Edward Burnell Sr Memorial, NDB RWY 24, Amdt 2A, CANCELED

Cold Bay, AK, Cold Bay, VOR/DME OR TACAN–A, Amdt 4, CANCELED

Fairbanks, AK, Fairbanks Intl, ILS OR LOC RWY 2L, ILS RWY 2L (SA CAT I), ILS RWY 2L (CAT II), ILS RWY 2L (CAT III), Amdt 10
Fairbanks, AK, Fairbanks Intl, RNAV (GPS) RWY 2R, Amdt 1
Fairbanks, AK, Fairbanks Intl, RNAV (GPS) RWY 20L, Amdt 1
Fairbanks, AK, Fairbanks Intl, RNAV (GPS) Y RWY 2L, Amdt 1
Fairbanks, AK, Fairbanks Intl, RNAV (GPS) Y RWY 20R, Amdt 1A
Fairbanks, AK, Fairbanks Intl, Takeoff Minimums and Obstacle DP, Amdt 6
Koyuk, AK, Koyuk Alfred Adams, NDB/DME RWY 1, Amdt 1B, CANCELED
Los Angeles, CA, Los Angeles Intl, RNAV (GPS) Y RWY 7L, Amdt 2D
Los Angeles, CA, Los Angeles Intl, RNAV (GPS) Y RWY 24L, Amdt 3
South Lake Tahoe, CA, Lake Tahoe, VOR/DME OR GPS–A, Amdt 3C, CANCELED
Boise, ID, Boise Air Terminal/Gowen Fld, LOC BC RWY 28L, Amdt 1A, CANCELED
Boise, ID, Boise Air Terminal/Gowen Fld, RNAV (GPS) Y RWY 10L, Amdt 3
Boise, ID, Boise Air Terminal/Gowen Fld, RNAV (GPS) Y RWY 10R, Amdt 2
Boise, ID, Boise Air Terminal/Gowen Fld, RNAV (GPS) Y RWY 28L, Amdt 5
Boise, ID, Boise Air Terminal/Gowen Fld, RNAV (GPS) Y RWY 28R, Amdt 6
Chicago/West Chicago, IL, DuPage, VOR RWY 10, Amdt 12C, CANCELED
Elkhart, IN, Elkhart Muni, VOR RWY 27, Amdt 15A, CANCELED
Elkhart, IN, Elkhart Muni, VOR/DME RWY 36, Amdt 4A, CANCELED
Gary, IN, Gary/Chicago Intl, RNAV (GPS) RWY 2, Orig
Gary, IN, Gary/Chicago Intl, VOR/DME OR GPS RWY 2, Amdt 7, CANCELED
Wabash, IN, Wabash Muni, Takeoff Minimums and Obstacle DP, Orig
Wabash, IN, Wabash Muni, VOR–A, Amdt 11
Portland, ME, Portland Intl Jetport, ILS OR LOC RWY 11, ILS RWY 11 (SA CAT I), ILS RWY 11 (CAT II), ILS RWY 11 (CAT III), Amdt 4
Portland, ME, Portland Intl Jetport, RNAV (GPS) RWY 11, Amdt 4
Portland, ME, Portland Intl Jetport, RNAV (GPS) RWY 18, Amdt 2
Portland, ME, Portland Intl Jetport, RNAV (GPS) RWY 29, Amdt 3
Portland, ME, Portland Intl Jetport, Takeoff Minimums and Obstacle DP, Amdt 7
Baudette, MN, Baudette Intl, VOR RWY 30, Amdt 10, CANCELED
Thief River Falls, MN, Thief River Falls Rgnl, NDB RWY 31, Amdt 2A, CANCELED
Poplarville, MS, Poplarville-Pearl River County, RNAV (GPS)–A, Orig
Poplarville, MS, Poplarville-Pearl River County, RNAV (GPS)–B, Orig
Poplarville, MS, Poplarville-Pearl River County, Takeoff Minimums and Obstacle DP, Orig
Asheville, NC, Asheville Rgnl, RADAR–1, Amdt 5A, CANCELED
Asheville, NC, Asheville Rgnl, Takeoff Minimums and Obstacle DP, Orig
Asheville, NC, Asheville Rgnl, Takeoff Minimums and Obstacle DP, Amdt 9, CANCELED
New Bern, NC, Coastal Carolina Regional, ILS OR LOC RWY 4, Amdt 1
New Bern, NC, Coastal Carolina Regional, RNAV (GPS) RWY 4, Amdt 1
Wilmington, NC, Wilmington Intl, TACAN–A, Amdt 1
Jamestown, ND, Jamestown Rgnl, NDB RWY 31, Amdt 6C, CANCELED
Charleston, SC, Charleston Executive, RNAV (GPS) RWY 27, Amdt 2B
Aberdeen, SD, Aberdeen Rgnl, NDB RWY 31, Amdt 10A, CANCELED
Dyersburg, TN, Dyersburg Rgnl, VOR/DME RWY 4, Amdt 4, CANCELED
Richfield, UT, Richfield Muni, RNAV (GPS) RWY 19, Amdt 1A
Roanoke, VA, Roanoke-Blacksburg Rgnl/Woodrum Field, Takeoff Minimums and Obstacle DP, Amdt 11

[FR Doc. 2015–28119 Filed 11–5–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31045; Amdt. No. 3668]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective November 6, 2015. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 6, 2015.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE., West Bldg., Ground Floor, Washington, DC, 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Richard A. Dunham III, Flight Procedure Standards Branch (AFS–420) Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK. 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary.

This amendment provides the affected CFRs, and specifies the SIAPs and

Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore— (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC on October 23, 2015.

John Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [AMENDED]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
10–Dec–15 ...	CT	New Haven	Tweed-New Haven	5/0067	10/6/15	RNAV (GPS) RWY 2, Orig-A.
10–Dec–15 ...	VA	Blacksburg	Virginia Tech/Montgomery Executive.	5/0384	10/6/15	RNAV (GPS) RWY 30, Orig.
10–Dec–15 ...	VA	Blacksburg	Virginia Tech/Montgomery Executive.	5/0385	10/6/15	LOC/DME RWY 12, Amdt 1A.
10–Dec–15 ...	VA	Blacksburg	Virginia Tech/Montgomery Executive.	5/0386	10/6/15	NDB–A, Amdt 4.
10–Dec–15 ...	SC	Loris	Twin City	5/1076	10/6/15	GPS RWY 26, Orig.
10–Dec–15 ...	LA	Bogalusa	George R Carr Memorial Air Fld.	5/1114	10/7/15	RNAV (GPS) RWY 18, Amdt 1A.
10–Dec–15 ...	AK	Kiana	Bob Baker Memorial	5/2959	10/13/15	RNAV (GPS) RWY 24, Orig.
10–Dec–15 ...	AK	Kiana	Bob Baker Memorial	5/2960	10/13/15	RNAV (GPS) RWY 6, Orig-A.
10–Dec–15 ...	AK	Wales	Wales	5/2969	10/13/15	RNAV (GPS) RWY 18, Orig-A.
10–Dec–15 ...	AK	Wales	Wales	5/2971	10/13/15	RNAV (GPS) RWY 36, Orig-A.
10–Dec–15 ...	UT	Cedar City	Cedar City Rgnl	5/3365	10/13/15	VOR RWY 20, Amdt 6B.
10–Dec–15 ...	KS	Topeka	Forbes Field	5/4370	10/19/15	VOR/DME OR TACAN RWY 21, Amdt 7.
10–Dec–15 ...	KS	Topeka	Forbes Field	5/4375	10/19/15	RNAV (GPS) RWY 31, Orig.
10–Dec–15 ...	KS	Topeka	Forbes Field	5/4401	10/19/15	VOR/DME OR TACAN RWY 3, Amdt 6A.
10–Dec–15 ...	KS	Topeka	Forbes Field	5/4402	10/19/15	RNAV (GPS) RWY 13, Orig.
10–Dec–15 ...	KS	Topeka	Forbes Field	5/4415	10/19/15	ILS OR LOC RWY 31, Amdt 9E.
10–Dec–15 ...	KS	Topeka	Forbes Field	5/4421	10/19/15	NDB RWY 13, Amdt 7A.
10–Dec–15 ...	NY	Hornell	Hornell Muni	5/4602	10/6/15	RNAV (GPS) RWY 36, Orig.
10–Dec–15 ...	TN	Dickson	Dickson Muni	5/4695	10/16/15	VOR/DME RWY 17, Amdt 4D.
10–Dec–15 ...	TN	Dickson	Dickson Muni	5/4696	10/16/15	NDB RWY 17, Amdt 2C.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
10–Dec–15 ...	NY	New York	John F Kennedy Intl	5/5037	10/16/15	COPTER RNAV (GPS) 028, Orig-A.
10–Dec–15 ...	WI	Appleton	Outagamie County Rgnl	5/6204	10/6/15	Takeoff Minimums and (Obstacle) DP, Orig.
10–Dec–15 ...	WV	Moundsville	Marshall County	5/6267	10/16/15	RNAV (GPS) RWY 24, Orig.
10–Dec–15 ...	WV	Moundsville	Marshall County	5/6268	10/16/15	RNAV (GPS) RWY 6, Orig-A.
10–Dec–15 ...	WV	Moundsville	Marshall County	5/6269	10/16/15	VOR/DME–A, Amdt 2.
10–Dec–15 ...	AK	Atqasuk	Atqasuk Edward Burnell Sr Memorial.	5/6532	10/13/15	RNAV (GPS) RWY 24, Amdt 1.
10–Dec–15 ...	AK	Atqasuk	Atqasuk Edward Burnell Sr Memorial.	5/6533	10/13/15	NDB RWY 6, Amdt 2A.
10–Dec–15 ...	AK	Atqasuk	Atqasuk Edward Burnell Sr Memorial.	5/6534	10/13/15	RNAV (GPS) RWY 6, Amdt 1.
10–Dec–15 ...	SC	Greenwood	Greenwood County	5/6959	10/6/15	NDB OR GPS RWY 27, Amdt 1A.
10–Dec–15 ...	SC	Hilton Head Island ..	Hilton Head	5/7041	10/16/15	VOR/DME A, Amdt 10.
10–Dec–15 ...	SC	Hilton Head Island ..	Hilton Head	5/7043	10/16/15	RNAV (GPS) RWY 3, Orig.
10–Dec–15 ...	SC	Hilton Head Island ..	Hilton Head	5/7044	10/16/15	RNAV (GPS) RWY 21, Orig.
10–Dec–15 ...	NY	Glens Falls	Floyd Bennett Memorial	5/7078	10/6/15	RNAV (GPS) RWY 30, Orig-A.
10–Dec–15 ...	NY	Glens Falls	Floyd Bennett Memorial	5/7079	10/6/15	RNAV (GPS) RWY 19, Amdt 1.
10–Dec–15 ...	NY	Glens Falls	Floyd Bennett Memorial	5/7080	10/6/15	ILS OR LOC RWY 1, Amdt 4.
10–Dec–15 ...	NY	Glens Falls	Floyd Bennett Memorial	5/7081	10/6/15	RNAV (GPS) RWY 12, Orig.
10–Dec–15 ...	NY	Glens Falls	Floyd Bennett Memorial	5/7082	10/6/15	RNAV (GPS) RWY 1, Amdt 1.
10–Dec–15 ...	AK	Tok	Tok Junction	5/7135	10/13/15	RNAV (GPS)-A, Orig-A.
10–Dec–15 ...	AK	Tok	Tok Junction	5/7136	10/13/15	RNAV (GPS) RWY 7, Orig-A.
10–Dec–15 ...	MN	Marshall	Southwest Minnesota Rgnl Marshall/Ryan Fld.	5/7677	10/6/15	Takeoff Minimums and (Obstacle) DP, Amdt 2.
10–Dec–15 ...	NY	Oneonta	Oneonta Muni	5/7752	10/16/15	LOC RWY 24, Amdt 2B.
10–Dec–15 ...	NY	Oneonta	Oneonta Muni	5/7753	10/16/15	RNAV (GPS) RWY 24, Orig-A.
10–Dec–15 ...	PA	Altoona	Altoona-Blair County	5/7925	10/19/15	VOR–A, Amdt 5A.
10–Dec–15 ...	AK	Coldfoot	Coldfoot	5/8238	10/13/15	RNAV (GPS) RWY 1, Amdt 1B.
10–Dec–15 ...	AK	Coldfoot	Coldfoot	5/8239	10/13/15	RNAV (GPS)-A, Orig-B.
10–Dec–15 ...	MI	Detroit	Coleman A Young Muni	5/8400	10/6/15	ILS OR LOC RWY 33, Amdt 14B.
10–Dec–15 ...	MN	Windom	Windom Muni	5/8581	10/6/15	RNAV (GPS) RWY 35, Orig.
10–Dec–15 ...	AR	Magnolia	Magnolia Muni	5/9813	10/6/15	Takeoff Minimums and (Obstacle) DP, Amdt 1.
10–Dec–15 ...	KS	Junction City	Freeman Field	5/9816	10/6/15	Takeoff Minimums and (Obstacle) DP, Amdt 2.

[FR Doc. 2015–28121 Filed 11–5–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Part 301

Instruments and Apparatus for Educational and Scientific Institutions

CFR Correction

In Title 15 of the Code of Federal Regulations, Parts 300 to 799, revised as of January 1, 2015, on page 10, in § 301.2, in paragraph (o), remove the term '', x-ray spectrometer'' in both places it appears.

[FR Doc. 2015–28281 Filed 11–5–15; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Part 301

Instruments and Apparatus for Educational and Scientific Institutions

CFR Correction

In Title 15 of the Code of Federal Regulations, Parts 300 to 799, revised as of January 1, 2015, on page 18, in § 301.8, in paragraph (b), remove the term ''Customs'' and add ''Customs and Border Protection'' in its place.

[FR Doc. 2015–28282 Filed 11–5–15; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Part 303

Watch, Watch Instruments, and Jewelry Program

CFR Correction

In Title 15 of the Code of Federal Regulations, Parts 300 to 799, revised as of January 1, 2015, on page 38, in § 303.17, in paragraph (c), remove the last sentence and add the following two sentences in its place: ''It is the responsibility of each program producer to make the appropriate data available to the Departments' officials for the calendar year for which the annual verification is being performed and no further data, from the calendar year for which the audit is being completed, will be considered for benefits at any time after the audit has been completed. In the event of discrepancies between the application and substantiating data before the audit is complete, the Secretaries shall determine which data

will be used in the calculation of the duty refund and allocations.''

[FR Doc. 2015–28284 Filed 11–5–15; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0643; FRL–9935–65–Region 9]

Approval of California Air Plan Revisions, Placer County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve a revision to the Placer County portion of the California State Implementation Plan (SIP). This revision concerns the necessary procedures to create emission reduction credits (ERCs) from the reduction of volatile organic compound (VOC), oxides of nitrogen (NOx), oxides of sulfur (SOx), particulate matter (PM), and carbon monoxide (CO) emissions due to the use and installation of a control device on stationary locomotive engines in rail yards. We are approving a local rule that provides administrative procedures for creating emissions reduction credits, consistent with Clean Air Act (CAA or the Act) requirements.

DATES: This rule is effective on January 5, 2016 without further notice, unless the EPA receives adverse comments by December 7, 2015. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2015–0643, by one of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.

2. *Email: steckel.andrew@epa.gov.*

3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you need to include CBI as part of your comment, please visit *http://www.epa.gov/dockets/comments.html* for further instructions. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. For the full EPA public comment policy and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/comments.html.*

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Nancy Levin, EPA Region IX, (415) 972–3848, *levin.nancy@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

Table of Contents

I. The State's Submittal

A. What rule did the State submit?

Table 1 lists the rule addressed by this action with the dates that it was adopted by the Placer County Air Pollution Control District (PCAPCD) and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULE

Local agency	Rule No.	Rule title	Adopted	Submitted
PCAPCD	515	Stationary Rail Yard Control Emission Reduction Credits.	02–19–2015	06–26–2015

On August 13, 2015, the EPA determined that the submittal for PCAPCD Rule 515 met the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review.

B. Are there other versions of this rule?

There are no previous versions of Rule 515 in the SIP, although the PCAPCD adopted an earlier version of this rule on October 9, 2008, and CARB submitted it to us on December 23, 2008. CARB withdrew the earlier version of Rule 515 on August 11, 2014.

C. What is the purpose of the submitted rule?

The purpose of Rule 515 is to provide owners of a rail yard located in Placer County with a mechanism for quantifying, certifying, and banking emission reductions from the installation and use of a control device that reduces emissions from locomotive engines in rail yards. Approval of Rule 515 into the SIP would allow these emission reductions to be used as offsets under PCAPCD's New Source Review (NSR) rule. The EPA's technical support document (TSD) has more information about this rule.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rule?

SIP rules must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193).

In addition, a rule of this type that generates emission reduction credits for use as offsets in the NSR program must

meet the NSR requirements for valid offsets (see section 173(c)) and meet the criteria set forth in the EPA's guidance concerning economic incentive programs.

Guidance and policy documents that we use to evaluate enforceability and other requirements consistently include the following:

1. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).

2. State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule,'' (the NOx Supplement), 57 FR 55620, November 25, 1992.

3. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook).

4. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).

5. New Source Review—Section 173(c) of the CAA and 40 CFR part 51, appendix S, ''Emission Offset Interpretative Ruling'' require certain sources to obtain emission reductions to offset increased emissions from new projects.

6. ''Improving Air Quality with Economic Incentive Programs,'' EPA–452/R–01–001, January 2001.

B. Does the rule meet the evaluation criteria?

We believe this rule is consistent with the relevant policy and guidance regarding enforceability and economic incentive programs; and ensures that the emission reductions are real, surplus, quantifiable, enforceable, and permanent. This rule includes detailed emissions quantification protocols and enforceable procedures that provide the necessary assurance that the emission reduction credits issued will meet the criteria for valid NSR offsets. The TSD has more information on our evaluation.

C. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, the EPA is fully approving the submitted rule because we believe it fulfills all relevant requirements. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted rule. If we receive adverse comments by December 7, 2015, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on January 5, 2016. This will incorporate the rule into the federally enforceable SIP.

Please note that if the EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, the EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the CARB Regulations described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 5, 2016.

Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that the EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Sulfur dioxide, Carbon monoxide, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 25, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(463) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(463) Amended regulations for the following APCDs were submitted on June 26, 2015 by the Governor's designee.

(i) *Incorporation by reference.*

(A) Placer County Air Pollution Control District.

(*1*) Rule 515, ''Stationary Rail Yard Control Emission Reduction Credits,'' amended on February 19, 2015.

[FR Doc. 2015–28274 Filed 11–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2015–0428; FRL–9932–61–Region 8]

Air Plan Approval; WY; Update to Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; administrative change.

SUMMARY: The Environmental Protection Agency (EPA) is updating the materials that are incorporated by reference (IBR) into the Wyoming State Implementation Plan (SIP). The Regulations affected by this update have been previously submitted by the Wyoming Department of Environmental Quality and approved by the EPA. In this action, the EPA is also notifying the public of corrections to typographical errors and minor formatting changes to the IBR tables. This update affects the SIP materials that are available for public inspection at the EPA Regional Office.

DATES: This action is effective November 6, 2015.

ADDRESSES: The EPA has established a docket for this action under Docket Identification Number EPA–R08–OAR–2015–0428. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in the hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at EPA Region 8, Office of Partnership and Regulatory Assistance, Air Program, 1595 Wynkoop Street, Denver, Colorado 80202–1129. The EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. An electronic copy of the State's SIP compilation is also available at *http://www.epa.gov/region8/air/sip.html.*

FOR FURTHER INFORMATION CONTACT: Kathy Ayala, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6142, *ayala.kathy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The SIP is a living document which a state revises as necessary to address its unique air pollution problems. Therefore, the EPA, from time to time, must take action on SIP revisions containing new and/or revised regulations as being part of the SIP. On May 22, 1997 (62 FR 27968), the EPA revised the procedures for incorporating by reference Federally-approved SIPs, as a result of consultation between the EPA and the Office of the Federal Register (OFR). The description of the revised SIP document, IBR procedures and ''Identification of Plan'' format are discussed in further detail in the May 22, 1997, **Federal Register** document. On November 2, 2006 (71 FR 64460) the EPA published the revised format of the IBR material for Wyoming as of August 31, 2006. Today's action is an update to the November 2, 2006 document.

II. EPA Action

In this action, the EPA is announcing the update to the IBR material as of September 1, 2015. The EPA is also correcting typographical errors, including omission and other minor errors in subsection 52.2620, paragraphs (c), (d), and (e).

III. Good Cause Exemption

EPA has determined that today's action falls under the ''good cause'' exemption in section 553(b)(3)(B) of the Administrative Procedure Act (APA) which, upon a finding of ''good cause'' authorizes agencies to dispense with public participation, and section 553(d)(3), which allows an agency to make a rule effective immediately (thereby avoiding the 30-day delayed effective date otherwise provided for in the APA). Today's action simply updates the codification of provisions which are already in effect as a matter of law.

Under section 553 of the APA, an agency may find good cause where procedures are ''impractical, unnecessary, or contrary to the public interest.'' Public comment is ''unnecessary'' and ''contrary to the public interest'' since the codification only reflects existing law. Likewise, there is no purpose served by delaying the effective date of this action.

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Wyoming regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these

documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866. Because the agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute as indicated in the **SUPPLEMENTARY INFORMATION** section, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. This rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant. This rule does not involve technical standards; thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The rule also does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). This rule does not impose an information collection burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). EPA's compliance with these statutes and Executive Orders for the underlying rules are discussed in previous actions taken on the state's rules.

B. Submission to Congress and the Comptroller General

The Congressional Review Act (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This action simply codifies provisions which are already in effect as a matter of law in federal and approved state programs. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding and established an effective date of November 6, 2015. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This change to the identification of plan for Wyoming is not a ''major rule'' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

EPA has also determined that the provisions of section 307(b)(1) of the Clean Air Act pertaining to petitions for judicial review are not applicable to this action. Prior EPA rulemaking actions for each individual component of the Wyoming SIP compilation had previously afforded interested parties the opportunity to file a petition for judicial review in the United States Court of Appeals for the appropriate circuit within 60 days of such rulemaking action. Thus, EPA sees no need in this action to reopen the 60-day period for filing such petitions for judicial review for this ''Identification of plan'' update action for Wyoming.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: September 21, 2015.

Shaun L. McGrath,

Regional Administrator, Region 8.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart ZZ—Wyoming

■ 2. In § 52.2620 paragraphs (b), (c), (d) and (e) are revised to read as follows:

§ 52.2620 Identification of plan.

* * * * *

(b) *Incorporation by reference.* (1) Material listed in paragraphs (c) and (d) of this section with an EPA approval date prior to September 1, 2015, was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Material is incorporated as it exists on the date of the approval, and notice of any change in the material will be published in the **Federal Register**. Entries in paragraphs (c) and (d) of this section with EPA approval dates after September 1, 2015, will be incorporated by reference in the next update to the SIP compilation.

(2) EPA Region 8 certifies that the rules/regulations provided by EPA in the SIP compilation at the addresses in paragraph (b)(3) of this section are an exact duplicate of the officially promulgated state rules/regulations which have been approved as part of the SIP as of September 1, 2015.

(3) Copies of the materials incorporated by reference may be inspected at the EPA Region 8 Office, Office of Partnerships and Regulatory Assistance (OPRA), Air Program, 1595 Wynkoop Street, Denver, Colorado 80202–1129 and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(c) *EPA-approved regulations.*

Rule No.	Rule title	State effective date	EPA Effective date	Final rule citation/date	Comments
Chapter 01. Common Provisions.					
Section 02 ...	Authority	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 03 ...	Definitions	2/14/2013	12/23/2013	78 FR 69998, 11/22/13.	
Section 04 ...	Diluting and concealing emissions.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 05 ...	Unavoidable equipment malfunction.	1/30/2006	6/15/2010	75 FR 19886, 4/16/10.	
Section 06 ...	Credible Evidence	12/8/2000	6/15/2010	75 FR 19886, 4/16/10.	
Section 07 ...	Greenhouse gasses	2/14/2013	12/23/2013	78 FR 69998, 11/22/13.	
Chapter 02. Ambient Standards.					
Section 02 ...	Ambient standards for particulate matter.	9/7/2010	10/27/2014	79 FR 50840, 8/26/14.	
Section 03 ...	Ambient standards for nitrogen oxides.	12/19/2012	11/14/2014	79 FR 54910, 9/15/14.	
Section 04 ...	Ambient standards for sulfur oxides.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 05 ...	Ambient standards for carbon monoxide.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 06 ...	Ambient standards for ozone.	12/19/2012	11/14/2014	79 FR 54910, 9/15/14.	
Section 08 ...	Ambient standards for suspended sulfates.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 10 ...	Ambient standards for lead	9/7/2010	10/27/2014	79 FR 50840, 8/26/14.	
Section 12 ...	Incorporation by reference ..	12/19/2012	11/14/2014	79 FR 54910, 9/15/14.	
Chapter 03. General Emission Standards.					
Section 02 ...	Emission standards for particulate matter.	11/22/2013	11/20/2014	79 FR 62859, 10/21/14.	
Section 03 ...	Emission standards for nitrogen oxides.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 04 ...	Emission standards for sulfur oxides.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 05 ...	Emission standards for carbon monoxide.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 06 ...	Emission standards for volatile organic compounds.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 09 ...	Incorporation by reference ..	11/22/2013	3/23/2015	80 FR 9194, 2/20/15.	
Chapter 04. State Performance Standards for Specific Existing Sources.					
Section 02 ...	Existing sulfuric acid production units.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 03 ...	Existing nitric acid manufacturing plants.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Chapter 06. Permitting Requirements.					
Section 02 ...	Permit requirements for construction, modification, and operation.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 04 ...	Prevention of significant deterioration.	3/28/2012	1/6/2014	78 FR 73445, 12/06/13.	
Section 14 ...	Incorporation by reference ..	3/28/2012	1/6/2014	78 FR 73445, 12/06/13.	
Chapter 07. Monitoring Regulations.					
Section 02 ...	Continuous monitoring requirements for existing sources.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Chapter 08. Non-attainment Area Regulations.					
Section 02 ...	Sweetwater County particulate matter regulations.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 03 ...	Conformity of general federal actions to state implementation plans.	12/19/2012	9/16/2013	78 FR 49685, 8/15/13.	

Rule No.	Rule title	State effective date	EPA Effective date	Final rule citation/date	Comments
Section 05 ...	Incorporation by reference ..	12/19/2012	9/16/2013	78 FR 49685, 8/15/13.	
Chapter 09. Visibility Impairment/PM Fine Control.					
Section 02 ...	Visibility	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Chapter 10. Smoke Management.					
Section 02 ...	Open burning restrictions ...	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 03 ...	Wood waste burners	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Section 04 ...	Smoke management requirements.	4/5/2005	1/11/2013	77 FR 73926, 12/12/12.	
Chapter 12. Emergency Controls.					
Section 02 ...	Air pollution emergency episodes.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Chapter 13. Mobile Sources.					
Section 02 ...	Motor vehicle pollution control.	10/29/1999	8/27/2004	69 FR 44965, 7/28/04.	
Chapter 14. Emission Trading Program Regulations.					
Section 2	Western backstop sulfur dioxide trading program.	5/7/2008	1/11/2013	77 FR 73926, 12/12/12.	
Section 3	Sulfur dioxide milestone inventory.	5/7/2008	1/11/2013	77 FR 73926, 12/12/12.	
App A	Web Chapter 14, Section 2 Monitoring Protocols.	5/7/2008	1/11/2013	77 FR 73926, 12/12/12.	

(d) *EPA-approved source specific requirements.*

Regulation	Rule title	State effective date	EPA Effective date	Final rule citation/date	Comments
Black Hills Power and Light.	Order containing schedule for compliance, interim requirements, and monitoring and reporting requirements.	4/25/1979	8/1/1979	44 FR 38473, 7/2/79.	
FMC Corporation.	Order containing schedule for compliance, interim requirements, and monitoring and reporting requirements.	4/25/1979	8/1/1979	44 FR 38473, 7/2/79.	

(e) *EPA-approved nonregulatory provisions.*

Rule No.	Rule title	State effective date	EPA Effective date	Final rule citation/date	Comments
(01) I	Introduction	1/22/1972	6/30/1972	37 FR 10842, 5/31/72.	
(02) II	Legal Authority	2/19/1976	9/30/1976	41 FR 36652, 8/31/76.	
(03) III	Control Strategy	8/30/1984	11/11/1984	49 FR 39843, 10/11/84.	
(04) IV	Compliance Schedule	5/29/1973	8/2/1973	39 FR 24504, 7/03/73.	
(05) V	Emergency Episode Plan ...	8/26/1981	4/12/1981	47 FR 5892, 2/09/81.	
(06) VI	Air Quality Surveillance	12/13/1988	9/9/1988	55 FR 28197, 7/10/88.	
(07) VII	Review of New Sources and Modifications.	1/22/1972	6/30/1972	37 FR 10842, 5/31/72.	
(08) VIII	Source Surveillance	1/22/1972	6/30/1972	37 FR 10842, 5/31/72.	
(09) IX	Resources	1/22/1972	6/30/1972	37 FR 10842, 5/31/72.	
(10) X	Intergovernmental Cooperation.	1/22/1972	6/30/1972	37 FR 10842, 5/31/72.	

Rule No.	Rule title	State effective date	EPA Effective date	Final rule citation/date	Comments
(11) XI	Reports and Revisions	1/22/1972	6/30/1972	37 FR 10842, 5/31/72.	
(12) XII	Visibility Protection Class I	9/6/1988	3/17/1989	54 FR 6912, 2/15/89.	
(13) XIII	Sweetwater PM_{10} Attainment Plan.	1/25/1979	8/1/1979	44 FR 38473, 7/02/79.	
(14) XIV	Stack Height Good Engineering Practice.	12/9/1988	4/16/1989	54 FR 11186, 3/17/89.	
(15) XV	Small Business Assistance Program.	11/30/1993	8/19/1994	59 FR 31548, 6/20/94.	
(16) XVI	City of Sheridan—PM_{10} Air Quality Control and Maintenance Plan.	10/30/1990	7/25/1994	59 FR 32360, 6/23/94.	
(17) XVII	PSD Implementation for NOx.	11/20/1990	6/23/1991	56 FR 23811, 5/24/91.	
(18) XVIII	Interstate Transport, Wyoming Interstate Transport SIP satisfying the requirement of Section 110(a)(2)(D)(i) of the CAA for the 1997 8-hour ozone and $PM_{2.5}$ standards.	4/15/2008	7/7/2008	73 FR 26019, 5/08/08.	
(19) XIX	Powder River Basin PM_{10} Memorandum of Agreement.	12/22/1993	10/11/1995	60 FR 47290, 9/12/95.	
(20) XX	Addressing Regional Haze Visibility Protection For The Mandatory Federal Class I Areas Required Under 40 CFR 51.309.	1/7/2011	1/11/2013	77 FR 73926, 12/12/12.	
(21) XXI	Infrastructure SIP for Section 110(a)(2)—1997 $PM_{2.5}$ NAAQS.	3/26/2008	12/6/2013	78 FR 73445, 12/06/13.	
(22) XXII	Infrastructure SIP for Section 110(a)(2)—2006 $PM_{2.5}$ NAAQS.	8/19/2011	9/9/2015	80 FR 47857, 8/10/2015.	
(23) XXIII	Infrastructure SIP for Section 110(a)(2)—1997 Ozone NAAQ.	12/10/2009	8/24/2011	76 FR 44265, 7/25/11.	
(24) XXIV	Air Quality Control Regions and Emissions Inventory.	1/22/1972	6/30/1972	37 FR 10842, 5/31/72.	
(25) XXV	Wyoming State Implementation Plan for Regional Haze for 309(g).	1/12/2011	3/3/2014	79 FR 5032, 1/30/14	Excluding portions of the following: Chapters 6.4, 6.5.7, 6.5.8, and 7.5. EPA disapproved (1) the NO_X BART determinations for (a) Laramie River Units 1–3, (b) Dave Johnston Unit 3, and (c) Wyodak Unit 1; (2) the State's monitoring, record-keeping, and reporting requirements for BART units; and (3) the State's reasonable progress goals.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0740; FRL–9936–12]

Acetamiprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises existing tolerances with regional restrictions for residues of acetamiprid in or on clover, forage and clover, hay. Interregional Research Project Number 4 (IR–4) requested this tolerance action under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 6, 2015. Objections and requests for hearings must be received on or before January 5, 2016, and must

be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0740, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0740 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 5, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2014–0740, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, EPA/DC, (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 11, 2015 (80 FR 7559) (FRL–9921–94), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8307) by IR–4, IR–4 Project Headquarters, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.578 be amended by revising (increasing) tolerances for residues of the insecticide, acetamiprid (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N′*-cyano-*N*-methylethanimidamide, including its metabolites and degradates, in or on clover, forage from 0.10 to 0.3 parts per million (ppm) and clover, hay from 0.01 to 1.5 ppm. That document referenced a summary of the petition prepared by Nisso America Incorporated, the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the tolerance for clover, hay from what was requested. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . . ''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for acetamiprid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with acetamiprid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information

concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Acetamiprid is moderately toxic in acute lethality studies via the oral route of exposure and is minimally toxic via the dermal and inhalation routes of exposure. It is not an eye or skin irritant, nor is it a dermal sensitizer. Acetamiprid does not appear to have specific target organ toxicity. Generalized toxicity was observed as decreases in body weight, body weight gain, food consumption and food efficiency in all species tested. Generalized liver effects were also observed in mice and rats (hepatocellular vacuolation in rats and hepatocellular hypertrophy in mice and rats); the effects were considered to be adaptive. Other effects observed in the oral studies include amyloidosis of multiple organs in the mouse oncogenicity study, tremors in high dose females in the mouse subchronic study, and microconcretions in the kidney papilla and mammary hyperplasia in the rat chronic/oncogenicity study. No effects were observed in a dermal toxicity study in rabbits.

In the rat developmental study, fetal shortening of the 13th rib was observed in fetuses at the same dose level that produced maternal effects (reduced body weight and body weight gain and increased liver weights). In the developmental rabbit study, no developmental effects were observed in fetuses at doses that reduced maternal body weight and food consumption. In the reproduction study, decreased body weight, body weight gain, and food consumption were observed in parental animals while significant reductions in pup weights were seen in the offspring in both generations. Also observed were reductions in litter size, and viability and weaning indices among F_2 offspring as well as significant delays in the age to attain vaginal opening and preputial separation. In the developmental neurotoxicity study, parental effects were limited to decreased body weight and body weight gains, while the offspring effects noted were decreased body weights and body weight gains, decreased pre-weaning survival, and decreased maximum auditory startle response. In the acute neurotoxicity study, male and female rats displayed decreased motor activity, tremors, walking and posture abnormalities, dilated pupils, coldness to the touch and decreased grip strength and foot splay at the highest dose tested (HDT). There were clinical signs (decreases auditory startle, tremors) noted in rats and mice in the developmental neurotoxicity (DNT) and subchronic mouse studies. However, no neurotoxic effects were seen in the subchronic neurotoxicity study in rats. No neuropathology was observed in the toxicology studies.

In immunotoxicity studies performed in both sexes of rats and mice, no effects on the immune system were observed up to the highest dose, although significant reductions in body weight and body weight gain were noted at that dose.

Based on acceptable carcinogenicity studies in rats and mice, EPA has determined that acetamiprid is ''not likely to be carcinogenic to humans.'' The classification is based on (1) the absence of an increase in the incidence of tumors in a mouse carcinogenicity study; and (2) in a rat chronic/carcinogenicity study, the absence of a dose-response and the lack of a statistically significant increase in the mammary adenocarcinoma incidence by pair-wise comparison of the mid- and high- dose groups with the controls. There was no clear evidence of a mutagenic effect. Acetamiprid tested positive as a clastogen in an *in vitro* study but not in an *in vivo* study.

Specific information on the studies received and the nature of the adverse effects caused by acetamiprid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document, ''Subject: Acetamiprid. Human Health Risk Assessment. . . . .for Use of the Insecticide on Clover. . . . .Interval (Regional Registration)'' dated September 2, 2015 at pp. 42 in docket ID number EPA–HQ–OPP–2014–0740.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for acetamiprid used for human risk assessment is discussed in Unit III of the final rule published in the **Federal Register** of June 19, 2013 (78 FR 36671) (FRL–9391–2). However, in this tolerance rule, an additional new use is considered spot-on treatments for dogs. This newly proposed spot-on dog treatment to control fleas, ticks, and mosquitoes has potential for long-term exposure in residential indoor settings; therefore, the Agency selected additional endpoints and POD for the following exposure/scenarios: (1) Long-term (>6 months) incidental oral (hand-to-mouth in children) and (2) Long-term (>6 months) dermal. The endpoints/PODs selected were the same for both scenarios, based on effects observed in a rat chronic toxicity/oncogenicity study. In the study, at the LOAEL of 17.5 milligram/kilogram/day (mg/kg/day), decreased body weight and body weight gains were noted in females and hepatocellular vacuolation were noted in males. The NOAEL in the study is 7.1 mg/kg/day. The level of concern (LOC) is 100, based on an interspecies uncertainty factor of 10X, an intra-species uncertainty factor of 10X, and an Food Quality Protection Act (FQPA) safety factor of 1X.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acetamiprid, EPA considered exposure under the petitioned-for tolerances as well as all existing acetamiprid tolerances in 40 CFR 180.578. EPA assessed dietary exposures from acetamiprid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for acetamiprid. In estimating acute dietary exposure, EPA used the *Dietary Exposure Evaluation Model* software with the *Food Commodity Intake*

Database (DEEM–FCID), Version 3.16. This software uses 2003–2008 food consumption data from the US Department of Agriculture's (USDA's) *National Health and Nutrition Examination Survey, What We Eat in America* (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues in the assessment.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used DEEM–FCID, Version 3.16 and food consumption data from the 2003–2008 USDA NHANES/WWEIA. As to residue levels in food, EPA assumed 100 PCT and tolerance-level residues in the assessment.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that acetamiprid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for acetamiprid. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acetamiprid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acetamiprid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

EPA used the Food Quality Protection Act Index Reservoir Screening Tool (FIRST) and the Provisional Cranberry Model to generate surface water Estimated Drinking Water Concentrations (EDWCs) for use in the human health dietary risk assessment, while the Pesticide Root Zone Model for Groundwater (PRZM–GW) was used to generate groundwater EDWCs. The EDWCs of acetamiprid for acute exposures are 88.3 parts per billion (ppb) for surface water and 49.7 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 32.2 ppb for surface water and 45.0 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 88.3 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 45 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Acetamiprid is currently registered for the following uses that could result in residential exposures: Controlling a wide variety of indoor and outdoor insect pests using insecticide traps, crack and crevice treatments, soil treatments, and sprays. There is also a proposal to register acetamiprid for use by homeowners and commercial applicators as a monthly topical spot-on product for dogs only (not cats) to provide continuous protection against fleas, ticks, and mosquitoes. Residential exposure from proposed dog spot-on product is anticipated to result in dermal exposures for adult handlers. In addition, residential post-application dermal exposures are expected for adults and children 1 to 2 years old, and incidental oral exposures for children 1 to 2 years old. Inhalation exposure from the use of the spot-on product is considered negligible. Therefore, only dermal and incidental oral exposure were assessed for the proposed product.

Residential post-application exposures are expected to be short- (1 to 30 days), intermediate- (1 to 6 months) for the indoor treatments, and long-term (greater than 6 months) in duration from pet spot-on products. Residential handler exposure is assumed to be short-term due to the intermittent nature of homeowner spot-on applications (once-monthly treatment).

EPA assessed all these uses and conducted an aggregate residential exposure using the following assumptions:

Residential handler exposures: The Agency used short-term and intermediate-term dermal and inhalation exposure estimates to adult applicators from applications to mattresses, cracks and crevices in the aggregate risk assessment.

Post-application exposures: The Agency used short-term and intermediate-term dermal and inhalation exposure estimates to adults and children 1 to 2 years old from indoor applications (mattress treatment and crack and crevice treatments) and long-term dermal exposure estimates to adults and children 1 to 2 years old from contact with spot-on treated pets. In addition, the Agency used short-term and intermediate-term hand-to-mouth exposure estimates to children 1–2 years old from indoor applications and long-term hand-to-mouth exposure estimates from contact with spot-on treated pets.

EPA combines risk values resulting from separate routes of exposure when it is likely they can occur simultaneously based on the use pattern and the behavior associated with the exposed population, and if the hazard associated with the PODs is similar across routes. Residential post-application inhalation exposure is expected to be negligible from the proposed spot-on product; therefore, a quantitative assessment was not performed.

For children 1 to 2 years old, post-application dermal and incidental oral (hand-to-mouth) exposures were combined for short-, intermediate-, and long-term durations.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found acetamiprid to share a common mechanism of toxicity with any other substances, and acetamiprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that acetamiprid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants

and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The pre- and post-natal toxicity databases for acetamiprid include developmental toxicity studies in the rat and rabbit, developmental neurotoxicity (DNT) study in rats and a 2-generation reproduction toxicity study in rats. There was no evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses following *in utero* exposure to acetamiprid in the developmental toxicity studies. In the DNT and 2-generation reproduction studies there was no evidence of quantitative increased susceptibility observed. However, there was evidence of increased qualitative susceptibility of rat pups seen in the studies. In the DNT study in rats, although both maternal and offspring effects were seen at the same dose level, offspring animals were more severely affected. Decreased pre-weaning survival, and decreased maximum auditory startle response were observed in the presence of limited maternal toxicity (body weight effects). In the 2-generation reproduction study, effects observed were a decrease in mean body weight, body weight gain, and food consumption in the parental animals, and significant reductions in body weights in pups (both generations). Also, reduction in litter size and viability and weaning indices were seen among F_2 offspring, as well as significant delays in the age to attain vaginal opening and preputial separation. These offspring adverse effects were more severe than the parental effects.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicology database for acetamiprid is complete.

ii. Although there was evidence of increased qualitative susceptibility of the young in the DNT and 2-generation reproduction studies, there are clear NOAELs identified for the effects observed in the toxicity studies. Also, there was no evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses in the developmental toxicity studies.

iii. Acetamiprid produced signs of neurotoxicity in the high dose groups in the acute and developmental neurotoxicity studies in rats and the subchronic toxicity study in mice. However, no neurotoxic findings were reported in the subchronic neurotoxicity study in rats. Additionally, there are clear NOAELs identified for the effects observed in the toxicity studies. The doses and endpoints selected for risk assessment are protective and account for all toxicological effects observed in the database, including neurotoxicity.

iv. EPA has used conservative assumptions in the exposure (food, drinking water, and residential) assessment, including the use of 100 PCT assumptions, tolerance-level residue values, and upper-bound estimates of potential exposure through drinking water. In addition, the residential exposure assessment was conducted such that residential exposure and risk will not be underestimated. The aggregate exposure and risk estimates considered are expected to over-estimate the actual exposure and risk anticipated, based on the current and proposed use patterns; no risk estimates of concern were identified.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to acetamiprid will occupy 67% of the aPAD for children 1–2 years old, the population subgroup receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions discussed in this unit for chronic exposure, EPA has concluded that chronic exposure to acetamiprid from food and water will utilize 61% of the cPAD for children 1–2 years old, the population subgroup receiving the greatest exposure. Based on the explanation in Unit III.C.3., adult aggregate exposures reflect background exposure from food and water, plus long-term post-application dermal exposure from contact with dogs following spot-on treatment. For children 1–2 years old, long-term aggregate assessment reflects post-application dermal and hand-to-mouth (incidental) exposures from contact with spot-on treated dogs. The chronic dietary exposure and post-application pet spot-on residential exposure were aggregated and compared to the long-term POD. Adult and children long-term aggregate MOEs were 570 and 100, respectively, are ≥100, and indicate that risk estimates are not of concern. The chronic dietary exposure estimates are highly conservative, assuming tolerance-level residues and 100 PCT for all commodities. Therefore, EPA also considers the aggregate MOEs to be conservative estimates.

3. *Short- and Intermediate-term risk.* Short-term and intermediate aggregate exposure take into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Acetamiprid is currently registered for uses that could result in short- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to acetamiprid. Toxicological endpoints and POD for assessing short- and intermediate-term risks associated with exposure to acetamiprid are identical. Therefore, separate assessments are not being conducted for these durations. Using the exposure assumptions described in this unit for short- and intermediate-term exposures which represent the combined short- and intermediate-term food, water, and residential exposures aggregate. Additionally, for adults, reflect dermal and inhalation exposures from applications to mattresses, cracks and crevices, and for children 1–2 years old short- and intermediate- term aggregate assessment reflects dermal, inhalation, and hand-to-mouth exposures from post-application exposures following indoor applications.

EPA concluded the combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs of 300 for adults and 110 for children. Both short- and intermediate-term aggregate MOEs are ≥100, and indicate that risks are not of concern. The chronic dietary exposure estimates are highly conservative, assuming tolerance-level residues and 100 PCT for all commodities. Therefore, EPA also considers the aggregate MOEs to be conservative estimates.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two

adequate rodent carcinogenicity studies, acetamiprid is classified as ''not likely to be carcinogenic to human'' and not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to acetamiprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available to enforce the tolerance expression including; (1) gas chromatography with electron capture detection (GC/ECD) and (2) high-performance liquid chromotography (HPLC) with tandem mass spectrometric detection liquid chromotography/mass spectrometry/mass spectrometry (LC/MS/MS).

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for acetamiprid in or on clover, forage or clover, hay.

C. Response to Comments

One comment expressed concern generally for pesticide residues remaining on harvested food crops and potential human health concerns. The commenter further states that ''it is the responsibility of our government to protect American consumers for being harmed by the food they eat and that this action is a step in the right direction for establishing a safer, healthier food system . . . .'' The Agency agrees with these comments.

D. Revisions to Petitioned-For Tolerances

Available and relevant field trial data support a clover tolerance of 2.0 ppm, instead of the proposed tolerance of 1.5 ppm, in clover hay. The petitioner used residues in clover hay from all field trials which included pre-harvest intervals (PHIs) ranging from 27 to 63 days to calculate the proposed 1.5 ppm tolerance level. Since the proposed labeling stipulates a PHI of 30 days, EPA utilized only those residue data for clover hay collected at PHIs of 27–32 days as the input dataset for the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedure, which yielded a clover hay tolerance level at 2.0 ppm.

In clover forage, the recommended tolerance level includes an additional significant figure (0.30 ppm rather than 0.3 ppm). This is in order to avoid the situation where rounding of a residue result to the level of precision of the tolerance expression would be considered non-violative (such as 0.34 ppm being rounded to 0.3 ppm).

V. Conclusion

Therefore, revised tolerances with regional restrictions are established for residues of the insecticide acetamiprid, (1*E*)–*N*–[(6–chloro–3–pyridinyl)methyl]–*N*±-cyano–*N*-methylethanimidamide, including its metabolites and degradates, in or on clover, forage at 0.30 ppm and clover, hay at 2.0 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 29, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.578, revise the tolerance for commodities in the table in paragraph (c) to read as follows:

§ 180.578 Acetamiprid; tolerances for residues.

* * * * *

(c) * * *

Commodity	Parts per million
Clover, forage	0.30
Clover, hay	2.0

* * * * *

[FR Doc. 2015–28356 Filed 11–5–15; 8:45 am]

BILLING CODE 6560–50–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1817 and 1852

NASA Federal Acquisition Regulation Supplement

AGENCY: National Aeronautics and Space Administration.

ACTION: Technical amendments.

SUMMARY: NASA is making technical amendments to the NASA FAR Supplement (NFS) to provide needed editorial changes.

DATES: *Effective:* November 6, 2015.

FOR FURTHER INFORMATION CONTACT: Manuel Quinones, NASA, Office of Procurement, Contract and Grant Policy Division, via email at *manuel.quinones@nasa.gov,* or telephone (202) 358–2143.

SUPPLEMENTARY INFORMATION:

I. Background

As part of NASA's retrospective review of existing regulations pursuant to section 6 of Executive Order 13563, Improving Regulation and Regulatory Review, NASA conducted a comprehensive review of its regulations and published two final rules in the **Federal Register**. The final rule published on March 12, 2015, (80 FR 12935) requires the following editorial changes:

- Renumber section 1817.7300 as 1817.7000 and section 1817.7302 as 1817.7002. The final rule published on March 12, 2015, redesignated subpart 1817.73 as 1817.70, but failed to address its subsections.
- Correct the clause date at section 1852.215–81.

List of Subject in 48 CFR Parts 1817 and 1852

Government procurement.

Manuel Quinones,

NASA FAR Supplement Manager.

Accordingly, 48 CFR parts 1817 and 1852 are amended as follows:

PART 1817—SPECIAL CONTRACTING METHODS

■ 1. The authority citation for part 1817 is revised to read as follows:

Authority: 51 U.S.C. 20113(a) and 48 CFR chapter 1.

Subpart 1817–70 [Amended]

1817.7300 and 1817.7302 [Redesignated as 1817.7000 and 1817.7002]

■ 2. Amend subpart 1817.70 by redesignating section 1817.7300 as 1817.7000 and section 1817.7302 as 1817.7002.

PART 1852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. The authority citation for part 1852 continues to read as follows:

Authority: 51 U.S.C. 20113(a) and 48 CFR chapter 1.

1852.215–81 [Amended]

■ 4. Amend section 1852.215–81 by removing ''FEB 1998'' and adding ''APR 2015'' in its place.

[FR Doc. 2015–28309 Filed 11–5–15; 8:45 am]

BILLING CODE 7510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 150615523–5973–03]

RIN 0648–XD998

Pacific Island Pelagic Fisheries; 2015 U.S. Territorial Longline Bigeye Tuna Catch Limits for Guam

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final specifications.

SUMMARY: In this final rule, NMFS specifies a 2015 limit of 2,000 metric tons (mt) of longline-caught bigeye tuna for Guam. NMFS will allow the territory to allocate up to 1,000 mt each year to U.S. longline fishing vessels in a specified fishing agreement that meets established criteria. As an accountability measure, NMFS will monitor, attribute, and restrict (if necessary) catches of longline-caught bigeye tuna, including catches made under a specified fishing agreement. These catch limits and accountability measures support the long-term sustainability of fishery resources of the U.S. Pacific Islands.

DATES: The final specifications are effective November 6, 2015, through December 31, 2015. The deadline to submit a specified fishing agreement pursuant to 50 CFR 665.819(b)(3) for review is December 7, 2015.

ADDRESSES: Copies of the fishery ecosystem plans are available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, fax 808–522–8226, or *www.wpcouncil.org.*

Copies of the environmental assessment (EA) and finding of no significant impact for this action, identified by NOAA–NMFS–2015–0077, are available from *www.regulations.gov,* or from Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

FOR FURTHER INFORMATION CONTACT: Jarad Makaiau, NMFS PIRO Sustainable Fisheries, 808–725–5176.

SUPPLEMENTARY INFORMATION: NMFS is specifying a catch limit of 2,000 mt of longline-caught bigeye tuna for Guam in 2015. NMFS is also authorizing the territory to allocate up to 1,000 mt of its 2,000 mt bigeye tuna limit to U.S.

longline fishing vessels permitted to fish under the Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific (FEP). The Western Pacific Fishery Management Council recommended these specifications.

NMFS will monitor catches of longline-caught bigeye tuna by the Guam longline fisheries, including catches made by U.S. longline vessels operating under specified fishing agreements. A specified fishing agreement must meet specific criteria set forth in 50 CFR 665.819 (Territorial catch and fishing effort limits), which also governs the procedures for attributing longline-caught bigeye tuna. When NMFS projects a territorial catch or allocation limit will be reached, NMFS will, as an accountability measure, prohibit the catch and retention of longline-caught bigeye tuna by vessels in the applicable territory (if the territorial catch limit is projected to be reached), and/or vessels in a specified fishing agreement (if the allocation limit is projected to be reached). These catch and allocation limits and accountability measures are identical to those that NMFS specified in 2014 (79 FR 64097, October 28, 2014). NMFS notes that there is a pending case in litigation—*Conservation Council for Hawai'i, et al.,* v. *NMFS* (D. Haw.), case no. 14–cv–528—that challenges the framework process allowing the U.S. Pacific Island territories to allocate a portion of their bigeye tuna catch limit to U.S. longline fishing vessels.

You may find additional background information on this action in the preamble to the proposed specifications published on August 24, 2015 (80 FR 51193).

Comments and Responses

On August 24, 2015, NMFS published the proposed specifications for the three U.S. Pacific territories (Commonwealth of Northern Mariana Islands (CNMI), Guam, and American Samoa) and request for public comments (80 FR 51193); the comment period closed on September 8, 2015. NMFS received comments from individuals, businesses, and non-governmental organizations on the proposed specifications and the draft EA. NMFS responded to comments on the proposed specifications for all three territories when it published the final 2015 bigeye tuna specifications for the CNMI (80 FR 61767, October 14, 2015), and does not repeat the comments and responses here.

Changes From the Proposed Specifications

In the proposed specifications published on August 24, 2015 (80 FR 51193), NMFS proposed to specify a catch limit of 2,000 mt of longline-caught bigeye tuna for each of the three U.S. Pacific territories. NMFS also proposed to authorize each territory to allocate up to 1,000 mt of its 2,000 mt bigeye tuna limit to U.S. longline fishing vessels permitted to fish under the FEP.

NMFS determined that the proposed catch and allocation limits were consistent to the maximum extent practicable with the enforceable policies of the approved coastal zone management programs of each of the three territories. At that time, the coastal management program of the CNMI concurred with this determination. The American Samoa coastal management program, however, requested an extension of time to review the proposed action. Under regulations at 15 CFR 930.41(b), NMFS approved the requested extension. Additionally, at that time, the Guam coastal management program also indicated that it was still reviewing the proposed specifications. For these reasons, NMFS implemented the 2015 limits only for the CNMI, effective October 9, 2015 (80 FR 61767, October 14, 2015).

On October 12, 2015, the Coastal Management Program of Guam concurred with the NMFS consistency determination. Therefore, in this action, NMFS will implement the 2015 limits for Guam. We will consider the American Samoa review of the CZMA federal consistency determination before implementing a 2015 limit for American Samoa.

Classification

The Regional Administrator, NMFS PIR, determined that this action is necessary for the conservation and management of Pacific Island fishery resources, and that it is consistent with the Magnuson-Stevens Fishery Conservation and Management Act and other applicable laws.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. NMFS published the factual basis for the certification in the proposed rule and does not repeat it here. NMFS received no comments on this certification. As a result, a regulatory flexibility analysis is not required, and none has been prepared.

There is good cause to waive the 30-day delay requirement of the Administrative Procedure Act, 5 U.S.C. 553(d)(3), and make this rule effective immediately upon publication in the **Federal Register**. NMFS closed the U.S. pelagic longline fishery for bigeye tuna in the WCPO on August 5, 2015, because the fishery reached the 2015 U.S. WCPO catch limit (80 FR 44883, July 28, 2015). However, after NMFS implemented the 2015 limits for the CNMI, effective October 9, 2015 (80 FR 61767, October 14, 2015), the Governor of the CNMI immediately transmitted a specified fishing agreement that NMFS determined met the criteria set forth in 50 CFR 665.819 (Territorial catch and fishing effort limits). As a result, U.S. vessels identified in the CNMI specified fishing agreement may retain and land bigeye tuna up to the amount 1,000 mt allocated.

Should the fishery harvest the 1,000 mt allocation limit provided by the CNMI agreement before this rule becomes effective, NMFS would prohibit vessels from entering into specified fishing agreements with Guam during that period. Such delay could disrupt fishing operations and have negative financial effects on the fishing community, including vessels, restaurants, and other seafood-related businesses. This action is intended to ameliorate the potential for such impacts. Furthermore, NMFS has determined that this action is consistent with the conservation needs of target and non-target stocks, and would not result in significant impacts to the human environment. Finally, these specifications are only in effect through the end of 2015; delaying the effective date by thirty days would effectively reduce the available time to engage in fishing operations by half. Accordingly, NMFS finds it impracticable and contrary to the public interest to provide a 30-day delay in effectiveness for this rule.

This action is exempt from review under E.O. 12866 because it contains no implementing regulations.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 2, 2015.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2015–28298 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 80, No. 215
Friday, November 6, 2015

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 327

RIN 3064–AE40

Assessments

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of proposed rulemaking (NPR) and request for comment.

SUMMARY: Pursuant to the requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) and its authority under section 7 of the Federal Deposit Insurance Act (FDI Act), the FDIC proposes to impose a surcharge on the quarterly assessments of insured depository institutions with total consolidated assets of $10 billion or more. The surcharges would begin the calendar quarter after the reserve ratio of the Deposit Insurance Fund (DIF or fund) first reaches or exceeds 1.15 percent—the same time that lower regular deposit insurance assessment (regular assessment) rates take effect—and would continue through the quarter that the reserve ratio first reaches or exceeds 1.35 percent. The surcharge would equal an annual rate of 4.5 basis points applied to the institution's assessment base (with certain adjustments). The FDIC expects that these surcharges will commence in 2016 and that they should be sufficient to raise the reserve ratio to 1.35 percent in approximately eight quarters, *i.e.,* before the end of 2018. If, contrary to the FDIC's expectations, the reserve ratio does not reach 1.35 percent by December 31, 2018 (provided it is at least 1.15 percent), the FDIC would impose a shortfall assessment on insured depository institutions with total consolidated assets of $10 billion or more on March 31, 2019. Since the Dodd-Frank Act requires that the FDIC offset the effect of the increase in the reserve ratio from 1.15 percent to 1.35 percent on insured depository institutions with total consolidated assets of less than $10 billion, the FDIC would provide assessment credits to insured depository institutions with total consolidated assets of less than $10 billion for the portion of their regular assessments that contributed to growth in the reserve ratio between 1.15 percent and 1.35 percent. The FDIC would apply the credits each quarter that the reserve ratio is at least 1.40 percent to offset part of the assessments of each institution with credits.

DATES: Comments must be received by the FDIC no later than January 5, 2016.

ADDRESSES: You may submit comments on the NPR using any of the following methods:

- *Agency Web site: http://www.fdic.gov/regulations/laws/federal/propose.html.* Follow the instructions for submitting comments on the agency Web site.
- *Email: comments@fdic.gov.* Include RIN 3064–AE40 on the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m.
- *Public Inspection:* All comments received, including any personal information provided, will be posted generally without change to *http://www.fdic.gov/regulations/laws/federal/.*

FOR FURTHER INFORMATION CONTACT: Munsell W. St. Clair, Chief, Banking and Regulatory Policy Section, Division of Insurance and Research, (202) 898–8967; and Nefretete Smith, Senior Attorney, Legal Division, (202) 898–6851.

SUPPLEMENTARY INFORMATION:

I. Policy Objectives

The FDIC maintains a fund in order to assure the agency's capacity to meet its obligations as insurer of deposits and receiver of failed banks.[1] The FDIC considers the adequacy of the DIF in terms of the reserve ratio, which is equal to the DIF balance divided by estimated insured deposits. A higher minimum reserve ratio reduces the risk that losses from bank failures during a downturn will exhaust the DIF and reduces the risk of large, procyclical increases in deposit insurance assessments to maintain a positive DIF balance.

The Dodd-Frank Act, enacted on July 21, 2010, contained several provisions to strengthen the DIF.[2] Among other things, it: (1) Raised the minimum reserve ratio for the DIF to 1.35 percent (from the former minimum of 1.15 percent);[3] (2) required that the reserve ratio reach 1.35 percent by September 30, 2020;[4] and (3) required that, in setting assessments, the FDIC ''offset the effect of [the increase in the minimum reserve ratio] on insured depository institutions with total consolidated assets of less than $10,000,000,000.''[5]

Both the Dodd-Frank Act and the FDI Act grant the FDIC broad authority to implement the requirement to achieve the 1.35 percent minimum reserve ratio. In particular, under the Dodd-Frank Act, the FDIC is authorized to take such steps as may be necessary for the reserve ratio to reach 1.35 percent by September 30, 2020. Furthermore, under the FDIC's assessment authority in the FDI Act, the FDIC may impose special assessments in an amount determined to be necessary for any purpose that the FDIC may deem necessary.[6]

In the FDIC's view, the Dodd-Frank Act requirement to raise the reserve ratio to the minimum of 1.35 percent by September 30, 2020 reflects the importance of building the DIF in a timely manner to withstand future economic shocks. Increasing the reserve ratio faster reduces the likelihood of

[1] As used in this NPR, the term ''bank'' has the same meaning as ''insured depository institution'' as defined in section 3 of the FDI Act, 12 U.S.C. 1813(c)(2).

[2] Public Law 111–203, 334(e), 124 Stat. 1376, 1539 (12 U.S.C. 1817(note)).

[3] 12 U.S.C. 1817(b)(3)(B). The Dodd-Frank Act also removed the upper limit on the designated reserve ratio (which was formerly capped at 1.5 percent).

[4] 12 U.S.C. 1817(note).

[5] 12 U.S.C. 1817(note). The Dodd-Frank Act also: (1) Eliminated the requirement that the FDIC provide dividends from the fund when the reserve ratio is between 1.35 percent and 1.5 percent; (2) eliminated the requirement that the amount in the DIF in excess of the amount required to maintain the reserve ratio at 1.5 percent of estimated insured deposits be paid as dividends; and (3) granted the FDIC's authority to declare dividends when the reserve ratio at the end of a calendar year is at least 1.5 percent, but granted the FDIC sole discretion in determining whether to suspend or limit the declaration of payment or dividends, 12 U.S.C. 1817(e)(2)(A)–(B).

[6] 12 U.S.C. 1817(b)(5).

procyclical assessments, a key policy goal of the FDIC that is supported in the academic literature and acknowledged by banks.[7] In meeting the requirements of the Dodd-Frank Act, the FDIC considered the tradeoff between building the DIF sooner rather than later and the potential cost of higher additional assessments for banks with $10 billion or more in assets.

The purpose of the NPR is to meet the Dodd-Frank Act requirements in a manner that appropriately balances several considerations, including the goal of reaching the minimum reserve ratio reasonably promptly in order to strengthen the fund and reduce the risk of pro-cyclical assessments, the goal of maintaining stable and predictable assessments for banks over time, and the projected effects on bank capital and earnings. The proposed primary mechanism described below for meeting the statutory requirements—surcharges on regular assessments—would ensure that the reserve ratio reaches 1.35 percent without inordinate delay (in 2018) and would ensure that assessments are allocated equitably among banks responsible for the cost of these requirements.

II. Background

The Dodd-Frank Act gave the FDIC greater discretion to manage the DIF than it had previously, including greater discretion in setting the target reserve ratio, or designated reserve ratio (DRR), which the FDIC must set annually.[8] The FDIC Board of Directors (Board) has set a 2 percent DRR for each year starting with 2011.[9] The Board views the 2 percent DRR as a long-term goal.

By statute, the FDIC also operates under a Restoration Plan while the reserve ratio remains below 1.35 percent.[10] The Restoration Plan, originally adopted in 2008 and subsequently revised, is designed to ensure that the reserve ratio will reach 1.35 percent by September 30, 2020.[11]

In February 2011, the FDIC adopted a final rule that, among other things, contained a schedule of deposit insurance assessment rates that apply to regular assessments that banks pay. The FDIC noted when it adopted these rates that, because of the requirement making banks with $10 billion or more in assets responsible for increasing the reserve ratio from 1.15 percent to 1.35 percent, ''assessment rates applicable to all insured depository institutions need only be set high enough to reach 1.15 percent'' before the statutory deadline of September 30, 2020.[12] The February 2011 final rule left to a later date the method for assessing banks with $10 billion or more in assets for the amount needed to reach 1.35 percent.[13]

The FDIC also adopted a schedule of lower regular assessment rates in the February 2011 final rule that will go into effect once the reserve ratio of the DIF reaches 1.15 percent.[14] These lower regular assessment rates will apply to all banks' regular assessments. Regular assessments paid under the schedule of lower rates are intended to raise the reserve ratio gradually to the long-term goal of 2 percent.

In the FDIC's most recent semiannual update of the DIF's loss and income projections in October 2015, the FDIC projects that, under the current assessment rate schedule, the DIF reserve ratio is most likely to reach 1.15 percent in the first quarter of 2016, but may reach that level as early as the fourth quarter of this year.

III. Description of the Proposed Rule

A. Surcharges

To implement the requirements of the Dodd-Frank Act, and pursuant to the FDIC's authority in section 7 of the FDI Act,[15] the FDIC proposes to add a surcharge to the regular assessments of banks with $10 billion or more in assets. The surcharge would begin the quarter after the DIF reserve ratio first reaches or exceeds 1.15 percent and would continue until the reserve ratio first reaches or exceeds 1.35 percent, but no later than the fourth quarter of 2018.[16] The FDIC would notify those banks that would be subject to the surcharge in any quarter and the amount of such surcharge within the timeframe that applies to notification of regular assessment amounts.[17]

The FDIC proposes an annual surcharge rate of 4.5 basis points, which it expects will be sufficient to raise the reserve ratio from 1.15 percent to 1.35 percent in 8 quarters, before the end of 2018.

Banks Subject to the Surcharge

The banks subject to the surcharge (large banks) would be determined each quarter based on whether the bank was a ''large institution'' or ''highly complex institution'' for purposes of that quarter's regular assessments; however, an insured branch of a foreign bank whose assets as reported in its most recent quarterly Report of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks equaled or exceeded $10 billion would also be a large bank.[18] [19] [20]

[7] In 2011, the FDIC Board of Directors adopted a comprehensive, long-range management plan for the DIF that is designed to reduce procyclicality in the deposit insurance assessment system. Input from bank executives and industry trade group representatives favored steady, predictable assessments and found high assessment rates during crises objectionable. In addition, economic literature points to the role of regulatory policy in minimizing procyclical effects. See, for example: 75 FR 66272 and George G. Pennacchi, 2004. ''Risk-Based Capital Standards, Deposit Insurance and Procyclicality,'' FDIC Center for Financial Research Working Paper No. 2004–05.

[8] 12 U.S.C. 1817(b)(3)(A)(i).

[9] A DRR of 2 percent was based on a historical analysis as well as on the statutory factors that the FDIC must consider when setting the DRR. In its historical analysis, the FDIC analyzed historical fund losses and used simulated income data from 1950 to 2010 to determine how high the reserve ratio would have to have been before the onset of the two banking crises that occurred during this period to maintain a positive fund balance and stable assessment rates.

[10] 12 U.S.C. 1817(b)(3)(E).

[11] 75 FR 66293 (Oct. 27, 2010).

[12] 76 FR at 10683.

[13] See 76 FR 10673, 10683 (Feb. 25, 2011). The Restoration Plan originally stated that the FDIC would pursue rulemaking on the offset in 2011, 75 FR 66293 (Oct. 27, 2010), but in 2011 the Board decided to postpone rulemaking until a later date.

[14] 76 FR at 10717; see also 12 CFR 327.10(b). The FDIC adopted this schedule of lower assessment rates following its historical analysis of the long-term assessment rates that would be needed to ensure that the DIF would remain positive without raising assessment rates even during a banking crisis of the magnitude of the two banking crises of the past 30 years. On June 16, 2015, the Board adopted a notice of proposed rulemaking that would revise the risk-based pricing methodology for established small institutions, but would leave the overall range of rates and the assessment revenue expected to be generated unchanged. See 80 FR 40838 (July 13, 2015).

[15] 12 U.S.C. 1817.

[16] A final rule adopting this proposal will become effective on the first day of a calendar quarter. If a final rule adopting this proposal is not yet effective on the first day of the calendar quarter after the reserve ratio reaches 1.15 percent, surcharges would begin the first day of the calendar quarter in which a final rule becomes effective. Thus, for example, if the reserve ratio reaches 1.15 percent on March 31, 2016 and a final rule does not become effective until the third quarter of 2016, surcharges would begin effective July 1, 2016.

[17] As with regular assessments, surcharges would be paid one quarter in arrears, based on the bank's previous quarter data and would be due the last day of the quarter. (If the last day of the quarter was not a business day, the collection date would be the previous business day.) Thus, for example, if the surcharge were in effect for the first quarter of 2017, the FDIC would notify the banks that they are subject to the surcharge and the amount of each bank's surcharge obligation no later than June 15, 2017, 15 days before the first quarter 2017 surcharge payment due date of June 30, 2017 date (and the payment due date for first quarter 2017 regular assessments). The notice could be included in the banks' invoice for their regular assessment.

[18] In general, a ''large institution'' is an insured depository institution with assets of $10 billion or more as of December 31, 2006 (other than an insured branch of a foreign bank or a highly complex institution) or a small institution that reports assets of $10 billion or more in its quarterly reports of condition for four consecutive quarters. 12 CFR 327.8(f). If, after December 31, 2006, an institution classified as large reports assets of less than $10 billion in its quarterly reports of condition for four consecutive quarters, the FDIC will

Continued

Banks' Assessment Bases for the Surcharge

Pursuant to the broad authorities under the Dodd-Frank Act and the FDI Act, including the authority to determine the assessment amount, which includes defining an appropriate assessment base for the surcharge (the surcharge base), each large bank's surcharge base for any given quarter would equal its regular quarterly deposit insurance assessment base (regular assessment base) for that quarter with certain adjustments.[21] The first adjustment would add the regular assessment bases for that quarter of any affiliated banks [22] that are not large banks (affiliated small banks).[23] [24] The second adjustment would deduct $10 billion from the resulting amount to produce the surcharge base. In a banking organization that includes more than one large bank, however, the affiliated small banks' regular assessment bases and the $10 billion deduction would be apportioned among all large banks in the banking organization in proportion to each large bank's regular assessment base for that quarter.

Table 1.A gives an example of the calculation of the surcharge base for a banking organization that comprises three large banks but no affiliated small banks. Table 1.B gives an example of the calculation of the surcharge base for a banking organization that comprises three large banks and two affiliated small banks.

TABLE 1.A—APPLICATION OF $10 BILLION DEDUCTION WITHIN A BANKING ORGANIZATION

[$ in billions]

Affiliated large banks	Assessment base	Share of $10 billion deduction		Surcharge base
		%	$	
	A	(A/$116)=B	(B*$10)=C	A–C
#1	$25.00	21.6	$2.16	$22.84
#2	55.00	47.4	4.74	50.26
#3	36.00	31.0	3.10	32.90
Total	116.00	100	10.00	106.00

TABLE 1.B—APPLICATION OF $10 BILLION DEDUCTION FOR A BANKING ORGANIZATION CONTAINING LARGE AND SMALL BANKS

[$ in billions]

Affiliated large and small banks	Assessment base	Share of large bank assessment base		Addition of small bank assessment share		Share of $10 billion deduction		Surcharge base
		Calculation	B (%)	Calculation	C	Calculation	D	
Affiliated Large Bank #1	A1=$35.00	A1/(A1+A2+A3)	31.0	A1[B*(A4+A5)]	$39.18	(C/$126.50)*$10	$3.10	$36.08
Affiliated Large Bank #2	A2=$22.00	A2/(A1+A2+A3)	19.5	A2[B*(A4+A5)]	24.63	(C/$126.50)*$10	1.95	22.68
Affiliated Large Bank #3	A3=$56.00	A3/(A1+A2+A3)	49.6	A3[B*(A4+A5)]	62.69	(C/$126.50)*$10	4.96	57.73
Affiliated Small Bank #1	A4=$8.00							
Affiliated Small Bank #2	A5=$5.50							
Total	$126.50		100		126.50		10.0	116.50

reclassify the institution as small beginning the following quarter. 12 CFR 327.8(e). In general, a ''highly complex institution'' is: (1) an insured depository institution (excluding a credit card bank) that has had $50 billion or more in total assets for at least four consecutive quarters that is controlled by a U.S. parent holding company that has had $500 billion or more in total assets for four consecutive quarters, or controlled by one or more intermediate U.S. parent holding companies that are controlled by a U.S. holding company that has had $500 billion or more in assets for four consecutive quarters; or (2) a processing bank or trust company. If, after December 31, 2010, an institution classified as highly complex fails to meet the definition of a highly complex institution for four consecutive quarters (or reports assets of less than $10 billion in its quarterly reports of condition for four consecutive quarters), the FDIC will reclassify the institution beginning the following quarter. 12 CFR 327.8(g). In general, a ''small institution'' is an insured depository institution with assets of less than $10 billion as of December 31, 2006, or an insured branch of a foreign institution. 12 CFR 327.8(e).

[19] Assets for foreign banks are reported in FFIEC 002 report (Report of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks), Schedule RAL, line 3, column A.

[20] A large bank would also include a small institution if, while surcharges were in effect, the small institution was the surviving institution or resulting institution in a merger or consolidation with a large bank or if the small institution acquired all or substantially all of the assets or assumed all or substantially all of the deposits of a large bank.

[21] For purposes of regular assessments, the Dodd-Frank Act defines the assessment base with respect to an insured depository institution as an amount equal to:

(1) The average consolidated total assets of the insured depository institution during the assessment period; minus

(2) the sum of

(A) the average tangible equity of the insured depository institution during the assessment period, and

(B) in the case of an insured depository institution that is a custodial bank (as defined by the FDIC, based on factors including the percentage of total revenues generated by custodial businesses and the level of assets under custody) or a banker's bank (as that term is used in . . . (12 U.S.C. 24)), an amount that the FDIC determines is necessary to establish assessments consistent with the definition under section 7(b)(1) of the [Federal Deposit Insurance] Act (12 U.S.C. 1817(b)(1)) for a custodial bank or a banker's bank.

12 U.S.C. 1817(note).

[22] As used in this NPR, the term ''affiliate'' has the same meaning as defined in section 3 of the FDI Act, 12 U.S.C. 3(w)(6), which references the Bank Holding Company Act (''any company that controls, is controlled by, or is under common control with another company''). 12 U.S.C. 1841(k).

[23] The term ''small bank'' is synonymous with the term ''small institution'' as it is defined in 12 CFR 327.8(e) and used in existing portions of 12 CFR part 327 for purposes of regular assessments, except that it excludes: (1) an insured branch of a foreign bank whose assets as reported in its most recent most recent quarterly Call Report equaled or exceeded $10 billion; and (2) a small institution that, while surcharges were in effect, was the surviving or resulting institution in a merger or consolidation with a large bank or that acquired all or substantially all of the assets or assumed all or substantially all of the deposits of a large bank.

[24] As of June 30, 2015, 19 banking organizations had both large and small banks.

Adding the assessment bases of affiliated small banks to those of their large bank affiliates would serve two purposes. First, it would prevent large banks from reducing their surcharges (and shifting costs to other large banks) either by transferring assets and liabilities to existing or new affiliated small banks or by growing the businesses of affiliated small banks instead of the large bank.[25] Second, it would ensure that banking organizations of similar size (in terms of aggregate assessment bases) pay a similar surcharge. In other words, a banking organization with a large bank and one or more affiliated small banks would not have an advantage over a similarly sized banking organization that includes only a large bank but no affiliated small banks. For example, a banking organization that includes a large bank with $45 billion regular assessment base would pay the same as a banking organization that includes a large bank with a $35 billion regular assessment base and two affiliated small banks each with $5 billion regular assessment bases. In this example, the large bank in each organization would pay a surcharge based on a $35 billion assessment base (after deducting $10 billion from the $45 billion total in regular assessment bases).

Although the regular assessment bases of affiliated small banks would be added to those of the large banks for purposes of determining the surcharge base for large banks, only large banks would be assessed the quarterly surcharge and, as described below, all small banks, including small banks affiliated with large banks, would be entitled to credits for the portion of their assessments that contributed to the increase in the reserve ratio from 1.15 percent to 1.35 percent.

Deducting $10 billion from each large bank's assessment base for the surcharge would avoid a ''cliff effect'' for banks near the $10 billion asset threshold, thereby ensuring equitable treatment. Otherwise, a bank with just over $10 billion in assets would pay significant surcharges, while a bank with $9.9 billion in assets would pay none. The $10 billion reduction reduces incentives for banks to limit their growth to stay below $10 billion in assets, or to reduce their size to below $10 billion in assets, solely to avoid surcharges.

Like the proposed treatment of affiliated small banks, allocating the $10 billion deduction among large banks in a single banking organization that includes more than one large bank would ensure that banking organizations of a similar size (in terms of assessment bases) pay a similar surcharge. For example, a banking organization with multiple large banks would not have an advantage over other similarly sized banking organizations that have only one large bank because, instead of deducting $10 billion from each large bank in the organization, the deduction would be apportioned among the multiple affiliated large banks.

B. Shortfall Assessment

The FDIC expects that the proposed surcharges combined with regular assessments would raise the reserve ratio to 1.35 percent before December 31, 2018. It is possible, however, that unforeseen events could result in higher DIF losses or faster insured deposit growth than expected, or that banks may take steps to reduce or avoid quarterly surcharges. While not anticipated, these events or actions could prevent the reserve ratio from reaching 1.35 percent by the end of 2018. In this case, provided the reserve ratio is at least 1.15 percent, the FDIC would impose a shortfall assessment on large banks on March 31, 2019 and collect it on June 30, 2019.[26] The aggregate amount of the shortfall assessment would equal 1.35 percent of estimated insured deposits on December 31, 2018 minus the actual fund balance on that date.

If a shortfall assessment were needed, the FDIC proposes that it be imposed on any bank that was a large bank in any quarter during the period that surcharges are in effect (the surcharge period). Each large bank's share of any shortfall assessment would be proportional to the average of its surcharge bases (the average surcharge base) during the surcharge period. If a bank were not a large bank during a quarter of the surcharge period, its surcharge base would be deemed to equal zero for that quarter.[27] [28]

If a bank of any size acquired—through merger or consolidation—a large bank that had paid surcharges for one or more quarters, the acquiring bank would be subject to a shortfall assessment and its average surcharge base would be increased by the average surcharge base of the acquired bank.[29]

A large bank's share of the total shortfall assessment would equal its average surcharge base divided by the sum of the average surcharge bases of all large banks subject to the shortfall assessment.

Using an average of surcharge bases should ensure that anomalous growth or shrinkage in a large bank's assessment base would not subject it to a disproportionately large or small share of any shortfall assessment.

C. Payment Mechanism for the Surcharge and Any Shortfall Assessment

Each large bank would be required to take any actions necessary to allow the FDIC to debit its share of the surcharge from the bank's designated deposit account used for payment of its regular assessment. Similarly, each large bank subject to any shortfall assessment would be required to take any actions necessary to allow the FDIC to debit its share of the shortfall assessment from the bank's designated deposit account used for payment of its regular assessment. Before the dates that

[25] Some large banks, however, may be able to shift the burden of the surcharge by transferring assets and liabilities to a nonbank affiliate, or by shrinking or limiting growth.

[26] The FDIC would notify each bank subject to a shortfall assessment of its share of the shortfall assessment no later than 15 days before payment is due.

[27] Thus, for example, if a large bank were subject to a shortfall assessment because it had been subject to a surcharge for only one quarter of the surcharge period and assuming that the surcharge period lasted eight quarters, its surcharge base for seven quarters would be deemed to be zero and its average surcharge base would be its single positive surcharge base divided by eight.

[28] In the unlikely event that the reserve ratio had reached 1.15 percent (but not 1.35 percent) but had fallen below 1.15 percent on December 31, 2018 or had not reached 1.15 percent on or before December 31, 2018, the FDIC would impose a shortfall assessment at the end of the calendar quarter immediately following the calendar quarter in which the reserve ratio first reached or exceeded 1.15 percent. The aggregate amount of such a shortfall assessment would equal 0.2 percent of estimated insured deposits at the end of the calendar quarter in which the reserve ratio first reaches or exceeds 1.15 percent. If surcharges had been in effect, the shortfall assessment would be imposed on the banks described in the text using average surcharge bases as described in the text. If surcharges had never been in effect: (1) The shortfall assessment would be imposed on banks that were large banks as of the calendar quarter in which the reserve ratio first reached or exceeded 1.15 percent; and (2) an individual large bank's share of the shortfall assessment would be proportional to the average of what its surcharge bases were or would have been over the four calendar quarters ending with the calendar quarter in which the reserve ratio first reached or exceeded 1.15 percent. The shortfall assessment would be collected at the end of the quarter after the assessment was imposed. If the last day of the quarter was not a business day, the collection date would be the previous business day.

If the reserve ratio remains below 1.15 percent for a prolonged period after 2018 (and never reaches 1.35 percent), the FDIC Board may have to consider increases to regular assessment rates on all banks (in addition to the shortfall assessment on banks with $10 billion or more in assets) in order to achieve the minimum reserve ratio of 1.35 percent by the September 30, 2020 statutory deadline.

[29] With respect to surcharges and shares of any shortfall assessment, a surviving or resulting bank in a merger or consolidation would include any bank that acquires all or substantially all of another bank's assets or assumes all or substantially all of another bank's deposits.

payments were due, each bank would have to ensure that sufficient funds to pay its obligations were available in the designated account for direct debit by the FDIC. Failure to take any such action or to fund the account would constitute nonpayment of the assessment. Penalties for nonpayment would be as provided for nonpayment of a bank's regular assessment.[30]

D. Additional Provisions Regarding Mergers, Consolidations and Terminations of Deposit Insurance

First, under existing regulations, a bank that is not the resulting or surviving bank in a merger or consolidation must file a quarterly report of condition and income (Call Report) for every assessment period prior to the assessment period in which the merger or consolidation occurs. The surviving or resulting bank is responsible for ensuring that these Call Reports are filed. The surviving or resulting bank is also responsible and liable for any unpaid assessments on the part of the bank that is not the resulting or surviving bank.[31] The FDIC proposes that unpaid assessments would also include any unpaid surcharges and shares of a shortfall assessment.

Thus, for example, a large bank's first quarter 2017 surcharge (assuming that the surcharge was in effect then), which would be collected on June 30, 2017, would include the large bank's own first quarter 2017 surcharge plus any unpaid first quarter 2017 or earlier surcharges owed by any large bank it acquired between April 1, 2017 and June 30, 2017 by merger or through the acquisition of all or substantially all of the acquired bank's assets. The acquired bank would be required to file Call Reports through the first quarter of 2017 and the acquiring bank would be responsible for ensuring that these Call Reports were filed.

Second, existing regulations also provide that, for an assessment period in which a merger or consolidation occurs, total consolidated assets for the surviving or resulting bank include the total consolidated assets of all banks that are parties to the merger or consolidation as if the merger or consolidation occurred on the first day of the assessment period. Tier 1 capital (which is deducted from total consolidated assets to determine a bank's regular assessment base) is to be reported in the same manner.[32] The FDIC proposes that these provisions would also apply to surcharges and shares of any shortfall assessment.

Third, existing regulations provide that, when the insured status of a bank is terminated and the deposit liabilities of the bank are not assumed by another bank, the bank whose insured status is terminating must, among other things, continue to pay assessments for the assessment periods that its deposits are insured, but not thereafter.[33] The FDIC proposes that these provisions would also apply to surcharges and shares of any shortfall assessment.

Finally, in the case of one or more transactions in which one bank voluntarily terminates its deposit insurance under the FDI Act and sells certain assets and liabilities to one or more other banks, each bank must report the increase or decrease in assets and liabilities on the Call Report due after the transaction date and be assessed accordingly under existing FDIC assessment regulations. The bank whose insured status is terminating must, among other things, continue to pay assessments for the assessment periods that its deposits are insured. The FDIC proposes that the same process would also apply to surcharges and shares of any shortfall assessment.

E. Credits for Small Banks[34]

Under the proposal, while the reserve ratio remains between 1.15 percent and 1.35 percent, some portion of the deposit insurance assessments paid by small banks would contribute to increasing the reserve ratio. To meet the Dodd-Frank Act requirement to offset the effect on small banks of raising the reserve ratio from 1.15 percent to 1.35 percent, the FDIC proposes to provide assessment credits (credits) to these banks for the portion of their assessments that contribute to the increase from 1.15 percent to 1.35 percent.[35] For purposes of awarding credits, a small bank would be a bank that was not a large bank in a quarter within the ''credit calculation period.'' The ''credit calculation period'' covers the period beginning the quarter after the reserve ratio first reaches or exceeds 1.15 percent through the quarter that the reserve ratio first reaches or exceeds 1.35 percent (or December 31, 2018, if the reserve ratio has not reached 1.35 percent by then). Small bank affiliates of large banks would be small banks for purposes of this definition. The FDIC would apply credits to reduce future regular deposit insurance assessments.

Aggregate Amount of Credits

To determine the aggregate amount of credits awarded small banks, the FDIC would first calculate 0.2 percent of estimated insured deposits (the difference between 1.35 percent and 1.15 percent) on the date that the reserve ratio first reaches or exceeds 1.35 percent.[36] The amount that small banks contributed to this increase in the DIF through regular assessments—and the resulting aggregate amount of credits to be awarded small banks—would equal the small banks' portion of all large and small bank regular assessments during the credit calculation period times an amount equal to the increase in the DIF calculated above less surcharges. Surcharges would be subtracted from the increase in the DIF calculated above before determining the amount by which small banks contributed to that increase because surcharges are intended to grow the reserve ratio above 1.15 percent, not to maintain it at 1.15 percent.[37]

This method of determining the aggregate small bank credit implicitly assumes that all non-assessment revenue (for example, investment income) during the credit calculation period would be used to maintain the fund at a 1.15 percent reserve ratio and that regular assessment revenue would be used to maintain the fund at that reserve ratio only to the extent that other revenue was insufficient. Essentially, the method attributes reserve ratio growth to assessment revenue as much as possible and, with one exception, maximizes the amount of the aggregate small bank assessment credit. The exception is the assumption that all surcharge payments contribute to growth of the reserve ratio (to the

[30] See 12 CFR 308.132(c)(3)(v).

[31] 12 CFR 327.6(a).

[32] 12 CFR 327.6(b).

[33] 12 CFR 327.6(c).

[34] Large banks would receive no refund or credit if surcharges brought the reserve ratio above 1.35 percent. Thus, for example, if the reserve ratio were at 1.34 percent at the end of September 2018 and were at 1.37 percent at the end of 2018, large banks would receive no refund or credit for the two basis points in the reserve ratio above 1.35 percent. Similarly, large banks would receive no refund or credit if a shortfall assessment brought the reserve ratio above 1.35 percent.

[35] Small banks would not be entitled to any credits for the quarter in which a shortfall was assessed because large banks would be responsible for the entire remaining amount needed to raise the reserve ratio to 1.35 percent.

[36] If the reserve ratio had not reached 1.35 percent by December 31, 2018, the amount calculated would be the increase in the DIF needed to raise the DIF reserve ratio from 1.15 percent to the actual reserve ratio on December 31, 2018; that amount equals the DIF balance on December 31, 2018 minus 1.15 percent of estimated insured deposits on that date.

[37] If total assessments, including surcharges, during the credit calculation period were less than or equal to the increase in the DIF calculated above, the aggregate amount of credits to be awarded small banks would equal the aggregate amount of assessments paid by small banks during the credit calculation period.

extent of that growth), which is consistent with the purpose of the surcharge payments.

The FDIC projects that the aggregate amount of credits would be approximately $900 million, but the actual amount of credits may differ.

Individual Small Banks' Credits

Credits would be awarded to any bank that was a small bank at any time during the credit calculation period. An individual small bank's share of the aggregate credit (a small bank's credit share) would be proportional to its credit base, which would be defined as the average of its regular assessment bases during the credit calculation period.[38] [39] If, before the DIF reserve ratio reached 1.35 percent, a small bank acquired another small bank through merger or consolidation, the acquiring small bank's regular assessment bases for purposes of determining its credit base would include the acquired bank's regular assessment bases for those quarters during the credit calculation period that were before the merger or consolidation. No small bank could receive more in credits than it (and any bank acquired through merger or consolidation) paid during the credit calculation period in regular assessments while it was a small bank not subject to the surcharge.

By making a small bank's credit share proportional to its credit base rather than, for example, its actual assessments paid, the proposal reduces the chances that a riskier bank assessed at higher than average rates would receive credits for these higher rates, thus reducing the incentive for banks to take on higher risk.

Successors

If any bank acquired a bank with credits through merger or consolidation after the DIF reserve ratio reached 1.35 percent, the acquiring bank would acquire the credits of the acquired small bank. Other than through merger or consolidation, credits would not be transferrable. Credits held by a bank that failed or ceased being an insured depository institution would expire.

Use of Credits

After the reserve ratio reaches 1.40 percent (and provided that it remains at or above 1.40 percent), the FDIC would automatically apply a small bank's credits to reduce its regular deposit insurance assessment by 2 basis points (annual rate) times its regular assessment base, to the extent that the small bank had sufficient credits remaining to do so.[40] If a small bank's deposit insurance assessment rate were less than 2 basis points (annual rate), the credit would be used to fully offset the bank's quarterly deposit insurance assessment, but the assessment could never be less than zero.[41]

Under the FDI Act, the Board is required to adopt a restoration plan if the reserve ratio falls below 1.35 percent. Allowing credit use only when the reserve ratio is at or above 1.40 percent would provide a cushion for the DIF to remain above 1.35 percent in the event of rapid growth in insured deposits or an unanticipated spike in bank failures, and therefore would reduce the likelihood of triggering the need for a restoration plan.

Notices of Credits

As soon as practicable after the DIF reserve ratio reaches 1.35 percent or December 31, 2018, whichever occurs earlier, the FDIC would notify each small bank of the FDIC's preliminary estimate of the small bank's credit and the manner in which the credit was calculated, based on information derived from the FDIC's official system of records (the notice). The FDIC would provide the notice through FDICconnect or other means in accordance with existing practices for assessment invoices.[42]

After the initial notice, periodic updated notices would be provided to reflect the adjustments that may be made up or down as a result of requests for review of credit amounts, as well as subsequent adjustments reflecting the application of credits to assessments and any appropriate adjustment to a small bank's credits due to a subsequent merger or consolidation.

Requests for Review and Appeals

Proposed procedures under which a small bank that disagreed with the FDIC's computation of, or basis for, its credits could request review or appeal are set forth in Appendix 1.

[38] When determining the credit base, a small bank's assessment base would be deemed to equal zero for any quarter in which it was a large bank.

[39] Call Report amendments after the payment date for the final quarter of the surcharge period would not affect an institution's credit share.

[40] The amount of credits applied each quarter would not be recalculated as a result of amendments to the quarterly Call Reports or the quarterly Reports of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks pertaining to any quarter in which credits have been applied.

[41] The FDIC expects that few small banks will have credits remaining after 12 quarters of credit use. Any remaining credits after 12 quarters of credit use would be used to fully offset a bank's entire deposit insurance assessments in future quarters until credits were exhausted, as long as the reserve ratio exceeded 1.40 percent.

[42] See generally 12 CFR 327.2(b).

Appendix 1

Requests for Review and Appeals

A small bank could request review if it disagreed with the FDIC's computation of or basis for its credits within 30 days from: (1) The initial notice stating the FDIC's preliminary estimate of a small bank's credit and the manner in which the credit was calculated; or (2) any updated notice. A request for review would have to be filed with the FDIC's Division of Finance and be accompanied by any documentation supporting the bank's claim. If a bank did not submit a timely request for review, the bank would be barred from subsequently requesting review of its credit amount.

Upon receipt of a request for review, the FDIC also could request additional information as part of its review and require the bank to supply that information within 21 days of the date of the FDIC's request for additional information. The FDIC would temporarily freeze the amount of the proposed credit in controversy for the banks involved in the request for review until the request was resolved.

The FDIC's Director of the Division of Finance (Director), or his or her designee, would notify the requesting bank of the determination of the Director as to whether the requested change was warranted, whenever feasible: (1) Within 60 days of receipt by the FDIC of the request for revision; (2) if additional banks had been notified by the FDIC, within 60 days of the last response; or (3) if additional information had been requested by the FDIC, within 60 days of receipt of any such additional information, whichever was later.

The requesting bank that disagreed with that decision would be able to appeal its credit determination to the FDIC's Assessment Appeals Committee (AAC). An appeal to the AAC would have to be filed within 30 calendar days from the date of the Director's written determination. Notice of the procedures applicable to appeals would be included with that written determination.

Once the Director or the AAC, as appropriate, had made the final determination, the FDIC would make appropriate adjustments to credit amounts consistent with that determination and correspondingly provide the affected bank[s] with notice or update in the next invoice. Adjustments to credit amounts would not be applied retroactively to reduce or increase prior period assessments.

If the FDIC's responses to individual banks' requests for review of the preliminary estimate of their credit amount have not been finalized before the invoices for collection of assessments for the first calendar quarter following the quarter in which the reserve ratio reaches 1.40 percent, the FDIC would freeze the credit amounts in dispute while making any credits not in dispute available for use.

IV. Economic Effects

The FDIC estimates that it would collect approximately $10 billion in surcharges and award approximately $900 million in credits to small banks, although actual amounts could vary

from these estimates. The FDIC projects that a shortfall assessment would be unnecessary.

A. Accounting Treatment

The FDIC's analysis is that banks would not account for future surcharges or a possible shortfall assessment in the Call Report and other banking regulatory reports based on generally accepted accounting principles (GAAP) as a present liability or a recognized loss contingency within the meaning of Financial Accounting Standards Board Accounting Standards Codification (ASC) Topic 450—Contingencies because they do not relate to a current condition or event giving rise to a liability. Surcharges would become recognized loss contingencies in a then current quarter if (i) the bank is in existence during that quarter; and (ii) the bank is a large bank as of that quarter and therefore subject to the surcharge. Surcharges would be based on the bank's regular assessment bases in future periods, and recognized in regulatory reports for those periods, just as regular assessments are now (where each assessment is accounted for as a liability and expensed for the quarter it is assessed). A shortfall assessment would become a recognized loss contingency if (i) the reserve ratio had not reached 1.35 percent by the end of 2018; and (ii) the bank had been subject to a surcharge.

B. Capital and Earnings Analysis

Consistent with section 7(b)(2)(B) of the FDI Act, the analysis that follows estimates the effects of a 4.5 basis point surcharge on the equity capital and earnings of large banks.[43] Because small banks would not pay surcharges, surcharges would affect neither their capital nor their earnings; however, the analysis also estimates the effect of credits on small bank earnings.

Staff estimated the effect of a 4.5 basis-point surcharge on large banks' earnings in two ways. First, as a percentage of *adjusted earnings,* to take into account the savings projected to result from lower assessment rates implemented in the future when the reserve ratio reaches 1.15 percent. Second, as a percentage of *current earnings.* Current earnings are assumed to equal pre-tax income before extraordinary and other items from July 1, 2014 through June 30, 2015. Adjusted earnings are current earnings plus the savings to be gained by large banks from lower future assessments that will result from the lower assessment rate schedule will apply to regular assessments once the reserve ratio reaches 1.15 percent.

Assumptions and Data

The analysis is based on large banks as of June 30, 2015. As of that date, there were 108 large banks. Banks are merger-adjusted, except for failed bank acquisitions, for purposes of determining income.

Although the surcharge is expected to continue for 8 quarters, the analysis examines the effect of the surcharge over one year. Each large bank's surcharge base is calculated as of June 30, 2015. Data from July 1, 2014 through June 30, 2015 are used to calculate each large bank's current earnings and adjusted earnings. Capital for each large bank is the amount reported as of June 30, 2015. The analysis assumes that current earnings equal pre-tax income before extraordinary and other items from July 1, 2014 through June 30, 2015. Using this measure eliminates the potentially transitory effects of extraordinary items and taxes on profitability. In calculating the effect on capital and banks' ability to maintain a leverage ratio of at least 4 percent (the minimum capital requirement),[44] however, the analysis considers the effective after-tax cost of assessments.[45] The analysis assumes that the large banks do not transfer the one-time assessment to customers in the form of changes in borrowing rates, deposit rates, or service fees.

Projected Effects

For almost all large banks, the effective surcharge annual rate measured against large banks' regular assessment base would be less than the nominal surcharge rate of 4.5 basis points because of the $10 billion deduction. The FDIC projects that the net effect of lower assessment rates that go into effect when the reserve ratio reaches 1.15 percent and the imposition of the surcharge would result in lower assessments for nearly a third of all large banks. Specifically, the analysis estimates that 34 of the 108 large banks would pay lower assessments in the future.

The analysis reveals no significant capital effects from the surcharge. All large institutions would continue to maintain a 4 percent leverage ratio, at a minimum, both before and after the imposition of the surcharge.[46]

The annual surcharge would also represent only a small percentage of bank earnings for most large banks. In the aggregate, the annual surcharge would absorb 2.39 percent of total large bank adjusted earnings and 2.42 percent of total large bank current earnings.

Table 2.A shows that as of June 30, 2015, for 84 percent of all large banks (89 large banks) the surcharge would represent 3 percent or less of adjusted annual earnings. For more than 94 percent (100 large banks), the surcharge would represent 5 percent or less of adjusted annual earnings. Only 6 large banks' adjusted annual earnings would be affected by more than 5 percent, with the maximum effect on any single bank being 8.7 percent.

TABLE 2.A—THE EFFECT OF THE PROPOSAL ON ADJUSTED EARNINGS OF INDIVIDUAL LARGE BANKS

LARGE BANKS				
Surcharge relative to adjusted earnings	Population		Assets	
	Number	Percentage of total large banks	Total ($ in billions)	Percentage of total large banks
Between 0% to 1%	22	21	546	4
Between 1% to 2%	36	34	2,026	16
Between 2% to 3%	31	29	6,806	53
Between 3% to 4%	5	5	2,248	18

[43] Equity capital is defined as capital (stock and/or surplus earnings) that is free of debt, calculated as assets less liabilities.

[44] See 12 CFR 324.10(a).

[45] Since deposit insurance assessments are a tax-deductible operating expense, increases in assessment expenses can lower taxable income and decreases in the assessment rate can raise taxable income.

[46] Of the 108 large banks, 107 continue to maintain a leverage ratio of at least 4 percent. The other large bank is an insured branch of a foreign bank and does not report income in its quarterly financial filings, so its regulatory capital ratios cannot be calculated.

TABLE 2.A—THE EFFECT OF THE PROPOSAL ON ADJUSTED EARNINGS OF INDIVIDUAL LARGE BANKS—Continued

LARGE BANKS				
Surcharge relative to adjusted earnings	Population		Assets	
	Number	Percentage of total large banks	Total ($ in billions)	Percentage of total large banks
Between 4% to 5%	6	6	439	3
Over 5%	6	6	663	5
All Large Banks	106	100	12,728	100

Notes:
(1) Effect of Surcharge on Adjusted Earnings: Mean = 2.19%; Median = 1.92%; Max = 8.70%; Min = 0.04%
(2) Two large banks were excluded from the original population of 108. One large bank is an insured branch of a foreign bank and does not report income in its quarterly financial filings an the second large bank reported negative income.

When evaluating the effect of the surcharge on current earnings (that is, excluding the gains projected from lower future regular assessments), the effect of surcharges is slightly greater, as expected, but the results are not materially different. Table 2.B shows that, for 83 percent of large banks as of June 30, 2015, (88 large banks), the surcharge would represent 3 percent or less of current earnings. For 92 percent (98 large banks), the surcharge would represent 5 percent or less of current earnings. Only 8 large banks' current earnings would be affected by more than 5 percent, with the maximum effect on any single bank being 9.09 percent.

TABLE 2.B—THE EFFECT OF THE PROPOSAL ON CURRENT EARNINGS OF INDIVIDUAL LARGE BANKS

LARGE BANKS				
Surcharge relative to current earnings	Population		Assets	
	Number	Percentage of total large banks	Total ($ in billions)	Percentage of total large banks
Between 0% to 1%	22	21	546	4
Between 1% to 2%	35	33	2.007	16
Between 2% to 3%	31	29	6,810	43
Between 3% to 4%	5	5	2,232	18
Between 4% to 5%	5	5	401	3
Over 5%	8	8	733	6
All Large Banks	106	100	12,728	100

Notes:
(1) Impact of Surcharge on Current Earnings: Mean = 2.24%; Median = 1.95%; Max = 9.09%; Min = 0.04%
(2) Two large banks were excluded from the original population of 108. One large bank is an insured branch of a foreign bank and does not report income in its quarterly financial filings an the second large bank reported negative income.

Finally, credits would result in a small increase in small bank income. Almost every small bank would be able to use credits for at least five quarters. Small bank annual earnings, on average would increase by about 2.3 percent.

V. Evaluation of the Proposal

In 2011, when the FDIC adopted the lower assessment rate schedule that will go into effect when the reserve ratio reaches 1.15 percent, the FDIC projected that the reserve ratio would reach 1.15 percent at the end of 2018, not long before the statutory deadline for the reserve ratio to reach 1.35 percent.[47] The FDIC now projects that the reserve ratio is most likely to reach 1.15 percent in the first quarter of 2016, but may reach that level as early as the fourth quarter of this year, leaving additional time for the reserve ratio to reach the statutory target.

In all likelihood, under the proposal, the reserve ratio will reach 1.35 percent not later than the end of 2018. Reaching the statutory target reasonably promptly and in advance of the statutory deadline has benefits. First, it would strengthen the fund so that it could better withstand an unanticipated spike in losses from bank failures or the failure of one or more large banks.

Second, it would reduce the risk of the banking industry facing unexpected, large assessment rate increases in the future. Once the reserve ratio reaches 1.35 percent, the September 30, 2020 deadline will have been met and will no longer apply. If the reserve ratio later falls below 1.35 percent, even if that occurs before September 30, 2020, the FDIC would have a minimum of eight years to return the reserve ratio to 1.35 percent, reducing the likelihood of a large increase in assessment rates.[48] In contrast, if a spike in losses occurs before the reserve ratio reaches 1.35 percent, the Dodd-Frank Act deadline would remain in place, which could require that the banking industry—including banks with less than $10 billion in assets, if the reserve ratio fell below 1.15 percent—pay for the increase in the reserve ratio within a relatively short time. The proposal, therefore, reduces the risk of higher assessments being imposed at a time when the industry might not be as healthy and prosperous and can least afford to pay.

In addition, large banks would account for future surcharges in the Call Report and other banking regulatory reports based on GAAP as quarterly expenses, as they do for regular assessments, effectively spreading the

[47] 76 FR at 10684.

[48] See generally 12 U.S.C. 1817(b)(3)(E)(ii).

cost of the requirement over approximately eight quarters.

As discussed above, FDIC analysis reveals no significant capital effects on large banks from the surcharge. On average, the annual surcharge would absorb approximately 2.4 percent of large bank annual income.

VI. Alternatives Considered

Described below are several alternatives that the FDIC considered while developing this proposal. The FDIC also invites comment on these alternatives and any views as to whether and why an alternative, rather than the proposal, should be adopted as a final rule.

A. Shortfall Assessment Immediately After the Reserve Ratio Reaches 1.15 Percent

Description of the Alternative

As an alternative to the proposal, the FDIC considered foregoing surcharges and imposing a one-time assessment, similar to a shortfall assessment, on large banks at the end of the quarter after the DIF reserve ratio first reaches or exceeds 1.15 percent. Thus, for example, if the reserve ratio first reaches or exceeds 1.15 percent as of June 30, 2016, the FDIC would impose the one-time assessment on September 30, 2016, and collect it on December 30, 2016.[49] [50] The aggregate amount of a one-time assessment would equal 1.35 percent of estimated insured deposits as of the date that the reserve ratio first reaches or exceeds 1.15 percent minus the actual fund balance on that date.

The large banks that would be subject to a one-time assessment would be determined based upon their total consolidated assets for a period before the date of the NPR or their average total consolidated assets for several periods before the date of the NPR, such as average total consolidated assets over the last two quarters of 2014 and the first two quarters of 2015. While a large bank's assessment base for a one-time assessment would be determined similarly to the assessment base used for surcharges or a shortfall assessment, it would have to be determined based upon an assessment period before the date of the NPR or averaged over several assessment periods before the date of the NPR. Using assets and assessment bases for a period before the date of the NPR would prevent large banks from avoiding the assessment (and shifting costs to other large banks) by transferring assets to a nonbank affiliate or by shrinking or limiting growth.

In other respects, a one-time assessment would generally be treated the same as a shortfall assessment under the proposal.[51]

Because large banks would be assessed for the entire increase in the reserve ratio from 1.15 percent to 1.35 percent under a one-time assessment, small banks would not contribute to increasing the reserve ratio and would not receive credits.

Economic Effects of a One-Time Assessment on Banks

The FDIC estimates that a one-time assessment under this alternative would likely be approximately $13 billion, and would represent approximately 12 basis points of large banks' aggregate regular assessment base.

Accounting Treatment

As discussed above, the FDIC is of the view that large banks would account for surcharges as quarterly expenses and would not have to recognize in the Call Report and other banking regulatory reports based on GAAP a liability for them in advance. In contrast, the FDIC believes that a large bank's share of a one-time assessment would relate to a current period event or condition and could be probable and reasonably estimable. Therefore, under ASC Topic 450, if the FDIC adopted this alternative, large banks might have to recognize a liability for a one-time assessment. Recognition of such a liability could be as early as the date that the FDIC adopts a final rule (assuming that the FDIC adopts a one-time assessment in the final rule) or no later than when the FDIC determines that the reserve ratio has reached 1.15 percent.

Capital, Earnings and Liquidity Analysis

The FDIC estimates that, on average, a one-time assessment [52] would reduce large banks' annual earnings by approximately six-and-a-quarter percent,[53] would not materially affect these banks liquidity,[54] and would leave Tier 1 leverage ratios above the 4 percent regulatory minimum for all large banks.[55] The FDIC estimates that a one-time assessment would equal less than 10 percent of annual earnings for 90 large banks, would not exceed 20 percent of annual earnings for 13 such banks, and would exceed 20 percent of annual earnings for only 3 such banks. The FDIC estimates that a one-time assessment would represent, on average, 0.30 percent of large banks' liquid assets and would not be more than 1.07 percent of any large bank's liquid assets.

Evaluation of a One-Time Assessment

The alternative of a one-time assessment when the reserve ratio reaches 1.15 percent has several benefits. It would ensure that the DIF reserve ratio reaches 1.35 percent immediately after the reserve ratio reaches 1.15 percent rather than later, as would occur using surcharges, which would: (1) Strengthen the fund more quickly, so that it would be in an even better position to withstand the effects of an unanticipated spike in bank failures; and (2) further reduce the risk of the banking industry facing unexpected, large assessment rate increases in the future when it may not be as healthy and prosperous as it is currently.

On the other hand, large banks would have to recognize in the Call Report and other banking regulatory reports based on GAAP a large liability for a one-time assessment in advance, reducing income materially for the quarter in which the liability is recognized. In addition, because regular assessments would not contribute to increasing the reserve ratio from 1.15 percent to 1.35 percent if a one-time assessment were imposed, the amount collected from large banks in a one-time assessment is estimated to exceed the estimated total amount of proposed surcharges.

The FDIC considers a one-time assessment when the reserve ratio reaches 1.15 percent a reasonable alternative to the proposal in this NPR and is interested in comments on this approach. On balance, however, the

[49] As under the proposal, if the las day of the quarter was not a business day, the collection date would be the previous business day.

[50] A large bank might, however, have the option of paying (or be required to pay) its share of a one-time assessment in equal quarterly installments. One possibility would be to allow or require payment over four quarters; another would be to allow or require payment over eight quarters.

[51] However: (1) Call Report amendments received by the FDIC after 30 days before the collection date would not affect the determination of whether a bank met the definition of a large bank; and (2) Call Report amendments received by the FDIC after 30 days before the collection date would not affect the size of a large bank's assessment base for the one-time assessment.

[52] The estimate assumes an aggregate one-time assessment of approximately $12.7 billion, which is 0.2 percent of estimated insured deposits as of June 30, 2015.

[53] Earnings or income are annual income before assessments, taxes, and extraordinary items. Annual income is assumed to equal income from July 1, 2014 through June 30, 2015.

[54] Liquidity (or liquid assets) are defined as cash balances, federal funds and repos sold, and securities. Liquid assets are assumed to be the same as they were on June 30, 2015.

[55] Capital and liquid assets are assumed to be the same as they were on June 30, 2015. The estimate considers the effective after-tax cost of assessments in calculating the effect on capital. One covered bank is an insured branch of a foreign bank and is not required to report earnings and capital as part of its financial filings and, therefore, its Tier 1 leverage ratio cannot be determined.

FDIC considers the proposal the better alternative. As described above, in the FDIC's view, the proposal appropriately balances several considerations, including the goal of reaching the statutory minimum reserve ratio reasonably promptly in order to strengthen the fund and reduce the risk of pro-cyclical assessments, the goal of maintaining stable and predictable assessments for banks over time, and the projected effects on bank capital and earnings.

B. Delayed Shortfall Assessment Without Surcharges

A second alternative would be to impose no surcharges after the reserve ratio reaches 1.15 percent and if the reserve ratio does not reach 1.35 percent by a deadline sometime near the statutory deadline, to impose a shortfall assessment at the end of the following quarter, and to collect it at the end of the next quarter. Thus, for example, if the reserve ratio had not reached 1.35 percent by December 31, 2019, then the FDIC would impose a shortfall assessment on March 31, 2020, and collect it on June 30, 2020. The aggregate amount of such a shortfall assessment would equal the difference between 1.35 percent and the reserve ratio as of December 31, 2019 times the estimated insured deposits as of the deadline.

As under the proposal, to ensure that the effect on small banks of raising the reserve ratio from 1.15 percent to 1.35 percent was fully offset, the FDIC would provide assessment credits to small banks for the portion of their assessments that contributed to the increase in the reserve ratio from 1.15 percent to 1.35 percent. Assessment credits to small banks would be determined and applied as described above in the proposal.

Size of a Delayed Shortfall Assessment

The FDIC cannot accurately predict the size of a delayed shortfall assessment so far in advance of one. The size of a delayed shortfall assessment could vary widely depending on the condition of the banking industry and the economy. For example, if fund losses from failed banks remain relatively low, the amount of a delayed shortfall assessment could be less than the amount of aggregate surcharges under the proposal, since regular assessments would contribute longer toward raising the reserve ratio from 1.15 percent.[56] Thus, if estimated insured deposits grow to $7.65 trillion on December 31, 2019 (a growth rate of approximately 4.2 percent per year from June 30, 2015), and the reserve ratio is 1.26 percent at December 31, 2019, then a delayed shortfall assessment imposed on March 31, 2020, would be approximately $7.2 billion, less than the estimated $10 billion aggregate amount of surcharges under the proposal.

On the other hand, the amount of a delayed shortfall could be much larger than the amount of aggregate surcharges under the proposal, if, for example, fund losses increase. Thus, assuming again that estimated insured deposits grow to $7.65 trillion on December 31, 2019, if the reserve ratio as the result of increased losses is only 1.00 percent at December 31, 2019, a delayed shortfall assessment imposed on March 31, 2020, would be approximately $15.3 billion in order to raise the reserve ratio from 1.15 percent to 1.35 percent, more than the aggregate amount of proposed surcharges. Moreover, in this example, all banks, including small banks, would be responsible for approximately $11.5 billion in additional assessments to increase the reserve ratio from 1.00 percent to 1.15 percent. If losses between now and the end of 2019 were as large as they were during the recent financial crisis, a possibility that the FDIC is not predicting but cannot preclude, the amount of additional assessments that would be levied on all banks would be much larger than under the example. The actual amount of a delayed shortfall assessment would likely differ from any of these examples.

For similar reasons (the difficulty of predicting insured deposit growth and fund losses over a lengthy period, for example), the FDIC cannot accurately predict the aggregate amount of credits that would be awarded small banks under this alternative.

Evaluation of a Delayed Shortfall Assessment

For several reasons, the FDIC is not proposing this alternative. First, compared to either surcharges or a one-time assessment, a delayed shortfall assessment is likely to significantly delay the reserve ratio's reaching 1.35 percent, leaving the fund more exposed to a spike in losses from future bank failures.

Second, because the reserve ratio is likely to take significantly longer to reach 1.35 percent under this alternative, it increases the risk, as illustrated above, that banks—including small banks—might face sharp increases in assessments during a stressful period when they are less healthy and prosperous than they are now. As discussed earlier, once the reserve ratio reaches 1.35 percent, the September 30, 2020 deadline will have been met and will no longer apply. If the reserve ratio later falls below 1.35 percent, even if that occurs before September 30, 2020, the FDIC will have, under the FDI Act, a minimum of eight years to return the reserve ratio to 1.35 percent, reducing the likelihood of a large and potentially procyclical increase in assessment rates.[57]

C. Alternatives Based on Surcharges

The FDIC has considered other alternatives that are essentially variations on certain aspects of the surcharge proposal.

Method of Determining Surcharge Base

To determine a large bank's surcharge base for a quarter, the proposal would use the bank's regular assessment base, but would add the regular assessment bases for that quarter of any affiliated small banks and deduct $10 billion from the resulting amount to produce the surcharge base. In a banking organization that includes more than one large bank, however, the affiliated small banks' regular assessment bases and the $10 billion deduction would be apportioned among all large banks in the banking organization in proportion to each large bank's regular assessment base for that quarter. Including affiliated small banks' regular assessment bases in a large bank's surcharge base would prevent a large bank from reducing its surcharges either by transferring assets and liabilities to existing or new affiliated small banks or by growing the businesses of affiliated small banks instead of the large bank. It would also ensure that that banking organizations of similar size (in terms of aggregate assessment bases) pay a similar surcharge.

Rather than adding the entire regular assessment bases of affiliated small banks to those of large banks, an alternative would be to add to a large bank's assessment base each quarter only the amount of any increase in the regular assessment bases of affiliated small banks above their regular assessment bases as of June 30, 2015. Then $10 billion would also be deducted as under the proposal. Also, as under the proposal, in a banking organization that includes more than one large bank, the increase in affiliated small banks' regular assessment bases and the $10 billion deduction would be apportioned among all large banks in the banking organization in proportion

[56] The FDIC reached this conclusion assuming that the lower regular assessment rates scheduled to go into effect when the reserve ratio reaches 1.15 percent.

[57] See generally 12 U.S.C. 1817(b)(3)(E)(ii).

to each large bank's regular assessment base for that quarter.

Like the proposal, this alternative would prevent a large bank from reducing its surcharges by transferring assets and liabilities to existing or new affiliated small banks, or by growing the businesses of affiliated small banks instead of the large bank. Unlike the proposal, however, it would not ensure that that banking organizations of similar size (in terms of aggregate assessment bases) pay a similar surcharge. In addition, because the full amount of affiliated small banks' assessment bases would not be included in their large bank affiliates' surcharge bases, the risk that the reserve ratio will take longer than eight quarters to reach 1.35 percent or that a shortfall assessment would be needed would be increased, thus shifting some of the burden of surcharges to large banks without affiliated small banks.

The FDIC also considered alternatives that would impose various types of documentation requirements on large banks to explain changes in assessment bases between quarters during the surcharge period. Although such an approach may help prevent or discourage a large bank from reducing its surcharges by transferring assets and liabilities to existing or new affiliated small banks, it likely would not be as effective as the proposed approach. Moreover, a documentation-based approach would introduce additional complexity to the rule and impose burden and recordkeeping requirements on large banks that are not associated with the proposed option. Finally, unlike the proposal, this alternative would not ensure that that banking organizations of similar size (in terms of aggregate assessment bases) pay a similar surcharge. For these reasons, the FDIC does not favor an alternative based on imposing additional documentation requirements.

Method of Allocating Credits

The proposal would allocate credits to small banks based upon their assessment bases during the surcharge period. An alternative would be to allocate credits based upon a small bank's actual assessment payments. Doing so, however, would grant relatively larger credits to riskier banks, since these banks would have paid higher assessment rates. For this reason, the FDIC does not favor this alternative.

Length of Surcharge Period

Under the proposal, surcharges would start the quarter after the DIF reserve ratio first reaches or exceeds 1.15 percent, would be set at an annual rate of 4.5 basis points, and would continue until the reserve ratio first reaches or exceeds 1.35 percent, but no later than the fourth quarter of 2018. If necessary, a shortfall assessment would be imposed at the end of the first quarter of 2019.

An alternative would be to charge surcharges at a somewhat lower rate for a longer period and only impose a shortfall assessment if the reserve ratio had not reached 1.35 percent by a date nearer the statutory deadline (the end of 2019, for example).

The FDIC does not favor this alternative. In the FDIC's view, the proposal strikes the right balance after considering the statutory deadline for reaching the minimum reserve ratio and the goals of strengthening the fund's ability to withstand a spike in losses and minimizing the risk of larger assessments for the entire industry, as well as the effects on capital and earnings for surcharged banks.

VII. Effective Date

A final rule following this NPR would become effective on the first day of the calendar quarter that begins 30 or more days after publication of a final rule.

VIII. Request for Comment

The FDIC seeks comment on every aspect of this rulemaking, including the alternatives presented. In addition, the FDIC seeks comment on whether there are additional advantages, disadvantages or other effects of the proposal or an alternative that should be considered and why.

IX. Regulatory Analysis and Procedure

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires that each federal agency either certify that a proposed or final rule will not, if promulgated, have a significant economic impact on a substantial number of small entities or prepare an initial regulatory flexibility analysis of the proposal and publish the analysis for comment.[58] Certain types of rules, such as rules of particular applicability relating to rates or corporate or financial structures, or practices relating to such rates or structures, are expressly excluded from the definition of the term ''rule'' for purposes of the RFA.[59] This NPR relates directly to the rates imposed on insured depository institutions for deposit insurance. For this reason, the requirements of the RFA do not apply. Nonetheless, the FDIC is voluntarily undertaking a regulatory flexibility analysis and is seeking comment on it.

As of June 30, 2015, of the 6,348 insured commercial banks and savings institutions, there were 5,088 small insured depository institutions as that term is defined for purposes of the RFA (*i.e.*, those with $550 million or less in assets).[60] As described in the Supplementary Information section of the preamble, the purpose of this NPR is to meet the Dodd-Frank Act requirements to increase the DIF reserve ratio from 1.15 to 1.35 by September 30, 2020, and offset the effect of that increase on banks with less than $10 billion in total consolidated assets. The FDIC proposes to meet those requirements in a manner that appropriately balances several considerations, including the goal of reaching the statutory minimum reserve ratio reasonably promptly in order to strengthen the fund and reduce the risk of pro-cyclical assessments, the goal of maintaining stable and predictable assessments for banks over time, and the projected effects on bank capital and earnings. Both the Dodd-Frank Act and the FDI Act grant the FDIC broad authority to implement the offset requirement.

The proposed rule would affect small entities only to the extent that they would be eligible for credits in exchange for their contributions toward raising the deposit insurance reserve ratio from 1.15 percent to 1.35 percent. For purposes of awarding credits, a small bank would be a bank that was not a large bank in a quarter within the credit calculation period. The FDIC is proposing to apply these credits to future regular assessments, resulting in estimated average savings of 2.2 percent of annual earnings. Thus, this initial RFA analysis demonstrates that, if adopted in final form, the proposed rule would not have a significant economic impact on a substantial number of small institutions within the meaning of those terms as used in the RFA and the FDIC so certifies.[61]

The proposed rule does not directly impose any ''reporting'' or ''recordkeeping'' requirements. The compliance requirements for the proposed rule would not exceed (and, in fact, would be the same as) existing compliance requirements for the current risk-based deposit insurance assessment system for small banks. The FDIC is

[58] See 5 U.S.C. 603, 604, 605.

[59] 5 U.S.C. 601.

[60] Throughout this RFA analysis, a ''small institution'' or ''small insured depository institution'' refers to an institution with assets of $550 million or less. As of June 30, 2015, one insured branch of a foreign bank also had less than $550 million in assets.

[61] 5 U.S.C. 605.

unaware of any duplicative, overlapping or conflicting federal rules.

B. Riegle Community Development and Regulatory Improvement Act

The Riegle Community Development and Regulatory Improvement Act requires that the FDIC, in determining the effective date and administrative compliance requirements of new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations.[62]

This NPR proposes no additional reporting or disclosure requirements on insured depository institutions, including small depository institutions, or on the customers of depository institutions.

C. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act (''PRA'') of 1995, 44 U.S.C. 3501–3521, the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (''OMB'') control number. This NPR does not modify FDIC's Assessments information collection 3064–0057, Quarterly Certified Statement Invoice for Deposit Insurance Assessment. Therefore, no submission to OMB need be made.

D. The Treasury and General Government Appropriations Act, 1999Đ Assessment of Federal Regulations and Policies on Families

The FDIC has determined that the proposed rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, 112 Stat. 2681).

E. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act, Public Law 106–102, 113 Stat. 1338, 1471 (Nov. 12, 1999), requires the Federal banking agencies to use plain language in all proposed and final rulemakings published in the **Federal Register** after January 1, 2000. The FDIC invites your comments on how to make this proposal easier to understand. For example:

- Has the FDIC organized the material to suit your needs? If not, how could the material be better organized?
- Are the requirements in the proposed regulation clearly stated? If not, how could the regulation be stated more clearly?
- Does the proposed regulation contain language or jargon that is unclear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand?

List of Subjects in 12 CFR Part 327

Bank deposit insurance, Banks, Banking, Savings associations.

For the reasons set forth above, the FDIC proposes to amend part 327 as follows:

PART 327—ASSESSMENTS

■ 1. The authority for 12 CFR part 327 continues to read as follows:

Authority: 12 U.S.C. 1441, 1813, 1815, 1817–19, 1821.

§ 327.11 [Amended]

■ 2. Revise § 327.11 to read as follows:

§ 327.11 Surcharges and Assessments Required to Raise the Reserve Ratio of the DIF to 1.35 Percent.

(a) *Surcharge.—*

(1) *Institutions Subject to Surcharge.* The following insured depository institutions are subject to the surcharge described in this paragraph:

(i) Large institutions, as defined in § 327.8(f);

(ii) Highly complex institutions, as defined in § 327.8(g); and

(iii) Insured branches of foreign banks whose assets are equal to or exceed $10 billion, as reported in Schedule RAL of the branch's most recent quarterly Report of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks.

(2) *Surcharge Period.* The surcharge period shall begin the later of either the first day of the assessment period following the assessment period in which the reserve ratio of the DIF first reaches or exceeds 1.15 percent, or the assessment period ending on September 30, 2016. The surcharge period shall continue through the earlier of the assessment period ending December 31, 2018, or the end of the assessment period in which the reserve ratio of the DIF first reaches or exceeds 1.35 percent.

(3) *Notification of Surcharge.* The FDIC shall notify each insured depository institution subject to the surcharge of the amount of such surcharge no later than 15 days before such surcharge is due, as described in paragraph (a)(4) of this section.

(4) *Payment of Any Surcharge.* Each insured depository institution subject to the surcharge shall pay to the Corporation any surcharge imposed under paragraph (a) of this section in compliance with and subject to the provisions of §§ 327.3, 327.6 and 327.7. The payment date for any surcharge shall be the date provided in § 327.3(b)(2) for the institution's quarterly certified statement invoice for the assessment period in which the surcharge was imposed.

(5) *Calculation of Surcharge.* An insured depository institution's surcharge for each assessment period during the surcharge period shall be determined by multiplying 1.125 basis points times the institution's surcharge base for the assessment period.

(i) *Surcharge BaseÐInsured Depository Institution That Has No Affiliated Insured Depository Institution Subject to the Surcharge.* The surcharge base for an assessment period for an insured depository institution subject to the surcharge that has no affiliated insured depository institution subject to the surcharge shall equal:

(A) The institution's deposit insurance assessment base for the assessment period, determined according to § 327.5; plus

(B) The total deposit insurance assessment base for the assessment period, determined according to § 327.5, of any affiliated insured depository institutions that are not subject to the surcharge; minus

(C) $10 billion; provided, however, that an institution's surcharge base for an assessment period cannot be negative.

(ii) *Surcharge BaseÐInsured Depository Institution That Has One or More Affiliated Insured Depository Institutions Subject to the Surcharge.* The surcharge base for an assessment period for an insured depository institution subject to the surcharge that has one or more affiliated insured depository institutions subject to the surcharge shall equal:

(A) The institution's deposit insurance assessment base for the assessment period, determined according to § 327.5; plus

(B) The institution's portion of the total deposit insurance assessment base of all affiliated insured depository

[62] 12 U.S.C. 4802.

institutions that are not subject to the surcharge, determined according to§ 327.5, obtained by apportioning the total deposit insurance assessment base of institutions not subject to the surcharge, determined according to § 327.5, among all institutions and affiliated insured depository institutions that are subject to the surcharge, in proportion to the respective deposit insurance assessment bases, determined according to § 327.5, of the institutions subject to the surcharge; minus

(C) The institution's portion of a $10 billion deduction, obtained by apportioning the deduction among all institutions and affiliated insured depository institutions that are subject to the surcharge, in proportion to those institutions' respective deposit insurance assessment bases, determined according to § 327.5; provided, however, that an institution's surcharge base for an assessment period cannot be negative.

(D) For the purposes of this section, an affiliated insured depository institution is an insured depository institution that meets the definition of ''affiliate'' in section 3 of the FDI Act, 12 U.S.C. 1813(w)(6).

(6) *Effect of Mergers and Consolidations on Surcharge Base.*

(i) If an insured depository institution acquires another insured depository institution through merger or consolidation during the surcharge period, the acquirer's surcharge base will be calculated consistent with § 327.6 and § 327.11(a)(5). For the purposes of the surcharge, a merger or consolidation means any transaction in which an insured depository institution mergers or consolidates with any other insured depository institution, and includes transactions in which an insured depository institution either directly or indirectly acquires all or substantially all of the assets, or assumes all or substantially all of the deposit liabilities of any other insured depository institution, but there is not a legal merger or consolidation of the two insured depository institutions.

(ii) If an insured depository institution not subject to the surcharge is the surviving or resulting institution in a merger or consolidation with an insured depository institution that is subject to the surcharge or acquires all or substantially all of the assets, or assumes all or substantially all of the deposit liabilities, of an insured depository institution subject to the surcharge, then the surviving or resulting insured deposit institution or the insured depository institution that acquires such assets or assumes such deposit liabilities is subject to the surcharge.

(b) *Shortfall Assessment.*—

(1) *Institutions Subject to Shortfall Assessment.* Any insured depository institution that was subject to a surcharge under paragraph (a)(1) of this section, in any assessment period during the surcharge period described in paragraph (a)(2) of this section, shall be subject to the shortfall assessment described in paragraph (b) of this section. If surcharges under paragraph (a) of this section have not been in effect, the shortfall assessment described in paragraph (b) of this section will be imposed on insured depository institutions described in paragraph (a)(1) of this section as of the assessment period in which the reserve ratio of the DIF reaches or exceeds 1.15 percent.

(2) *Notification of Shortfall.* The FDIC shall notify each insured depository institution subject to the shortfall assessment of the amount of such institution's share of the shortfall assessment as described in paragraph (b)(5) of this section no later than 15 days before such shortfall assessment is due, as described in paragraph (b)(3) of this section.

(3) *Payment of Any Shortfall Assessment.* Each insured depository institution subject to the shortfall assessment shall pay to the Corporation such institution's share of any shortfall assessment as described in paragraph (b)(5) of this section in compliance with and subject to the provisions of §§ 327.3, 327.6 and 327.7. The payment date for any shortfall assessment shall be the date provided in § 327.3(b)(2) for the institution's quarterly certified statement invoice for the assessment period in which the shortfall assessment is imposed.

(4) *Amount of Aggregate Shortfall Assessment.*—

(i) If the reserve ratio of the DIF is at least 1.15 percent but has not reached or exceeded 1.35 percent as of December 31, 2018, the FDIC shall impose a shortfall assessment on March 31, 2019, equal to 1.35 percent of estimated insured deposits as of December 31, 2018, minus the actual DIF balance as of that date.

(ii) If the reserve ratio of the DIF is less than 1.15 percent and has not reached or exceeded 1.35 percent by December 31, 2018, the FDIC shall impose a shortfall assessment equal to 0.2 percent of estimated insured deposits at the end of the assessment period immediately following the assessment period during which the reserve ratio first reaches or exceeds 1.15 percent.

(5) *Institutions' Shares of Aggregate Shortfall Assessment.* Each insured depository institution's share of the aggregate shortfall assessment shall be determined by apportioning the aggregate amount of the shortfall assessment among all institutions subject to the shortfall assessment in proportion to each institution's shortfall assessment base as described in this paragraph.

(i) *Shortfall Assessment Base if Surcharges Have Been in Effect.* If surcharges have been in effect, an institution's shortfall assessment base shall equal the average of the institution's surcharge bases during the surcharge period. For purposes of determining the average surcharge base, if an institution was not subject to the surcharge during any assessment period of the surcharge period, its surcharge base shall equal zero for that assessment period.

(ii) *Shortfall Assessment Base if Surcharges Have Not Been in Effect.* If surcharges have not been in effect, an institution's shortfall assessment base shall equal the average of what its surcharge bases would have been over the four assessment periods ending with the assessment period in which the reserve ratio first reaches or exceeds 1.15 percent. If an institution would not have been subject to a surcharge during one of those assessment periods, its surcharge base shall equal zero for that assessment period.

(6) *Effect of Mergers and Consolidations on Shortfall Assessment.*

(i) If an insured depository institution, through merger or consolidation, acquires another insured depository institution that paid surcharges for one or more assessment periods, the acquirer will be subject to a shortfall assessment and its average surcharge base will be increased by the average surcharge base of the acquired institution, consistent with paragraph (b)(5) of this section.

(ii) For the purposes of the shortfall assessment, a merger or consolidation means any transaction in which an insured depository institution mergers or consolidates with any other insured depository institution, and includes transactions in which an insured depository institution either directly or indirectly acquires all or substantially all of the assets, or assumes all or substantially all of the deposit liabilities of any other insured depository institution, but there is not a legal merger or consolidation of the two insured depository institutions.

(c) *Assessment Credits.*—

(1) *Eligible Institutions.* For the purposes of this paragraph (c) of this

section, an insured depository institution will be considered an eligible institution, if, for any assessment period during the credit calculation period, the institution was not subject to a surcharge under paragraph (a) of this section.

(2) *Credit Calculation Period.* The credit calculation period shall begin the assessment period after the reserve ratio of the DIF reaches or exceeds 1.15 percent, and shall continue through the earlier of the assessment period that the reserve ratio of the DIF reaches or exceeds 1.35 percent or the assessment period that ends December 31, 2018.

(3) *Determination of Aggregate Assessment Credit Awards to All Eligible Institutions.* The FDIC shall award an aggregate amount of assessment credits equal to the amount resulting from multiplying the *fraction of quarterly regular deposit insurance assessments paid by eligible institutions* during the credit calculation period and the amount by which the *DIF increase* exceeds total surcharges imposed under paragraph (b) of this section; provided, however, that the aggregate amount of assessment credits cannot exceed the aggregate amount of quarterly deposit insurance assessments paid by eligible institutions during the credit calculation period.

(i) *Fraction of Quarterly Regular Deposit Insurance Assessments Paid by Eligible Institutions.* The fraction of assessments paid by eligible institutions shall equal quarterly deposit insurance assessments, as determined under § 327.9, paid by eligible institutions during the credit calculation period divided by the total amount of quarterly deposit insurance assessments paid by all insured depository institutions during the credit calculation period, excluding the aggregate amount of surcharges imposed under paragraph (b) of this section.

(ii) *DIF Increase if the DIF Reserve Ratio Has Reached 1.35 Percent by December 31, 2018.* The DIF increase shall equal 0.2 percent of estimated insured deposits as of the date that the DIF reserve ratio first reaches or exceeds 1.35 percent.

(iii) *DIF Increase if the DIF Reserve Ratio Has Not Reached 1.35 Percent by December 31, 2018.* The DIF increase shall equal the DIF balance on December 31, 2018, minus 1.15 percent of estimated insured deposits on that date.

(4) *Determination of Individual Eligible Institutions' Shares of Aggregate Assessment Credit.*—

(i) *Assessment Credit Share.* To determine an eligible institution's assessment credit share, the aggregate assessment credits awarded by the FDIC shall be apportioned among all eligible institutions in proportion to their respective assessment credit bases, as described in paragraph (c)(5)(ii) of this section.

(ii) *Assessment Credit Base.* An eligible institution's assessment credit base shall equal the average of its quarterly deposit insurance assessment bases, as determined under § 327.5, during the credit calculation period. An eligible institution's credit base shall be deemed to equal zero for any assessment period during which the institution was subject to a surcharge under subsection (a).

(iii) *Limitation.* The assessment credits awarded to an eligible institution shall not exceed the total amount of quarterly deposit insurance assessments paid by that institution for assessment periods during any part of the credit calculation period that it was an eligible institution.

(5) *Effect of Merger or Consolidation on Assessment Credit Base.* If an eligible institution acquires another eligible institution through merger or consolidation before the reserve ratio of the DIF reaches 1.35 percent, the acquirer's quarterly deposit insurance assessment base (for purposes of calculating the acquirer's assessment credit base) shall be deemed to include the acquired institution's deposit insurance assessment base for the assessment periods prior to the merger or consolidation that the acquired institution was an eligible institution.

(6) *Effect of Call Report Amendments.* Amendments to the quarterly Reports of Condition and Income or the quarterly Reports of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks that occur subsequent to the payment date for the final assessment period of the credit calculation period shall not affect an eligible institution's credit share.

(7) *Award and Notice of Assessment Credits.*—

(i) *Award of Assessment Credits.* As soon as practicable after the earlier of either December 31, 2018, or the date on which the reserve ratio of the DIF reaches 1.35 percent, the FDIC shall notify an eligible institution of the FDIC's preliminary estimate of such institution's assessment credits and the manner in which the FDIC calculated such credits.

(ii) *Notice of Assessment Credits.* The FDIC shall provide eligible institutions with periodic updated notices reflecting adjustments to the institution's assessment credits resulting from requests for review or appeals, mergers or consolidations, or the FDIC's application of credits to an institution's quarterly deposit insurance assessments.

(8) *Requests for Review and Appeal of Assessment Credits.* Any institution that disagrees with the FDIC's computation of or basis for its assessment credits, as determined under paragraph (c) of this section, may request review of the FDIC's determination or appeal that determination. Such requests for review or appeal shall be filed pursuant to the procedures set forth in paragraph (d) of this section.

(9) *Successors.* If an insured depository institution acquires an eligible institution through merger or consolidation as described in paragraph (c)(5) of this section, after the reserve ratio of the DIF reaches 1.35 percent, the acquirer is successor to any assessment credits of the acquired institution. Other than through merger or consolidation, as described in paragraph (c)(5) of this section, credits awarded to an eligible institution under this paragraph (c) of this section are not transferable.

(10) *Mergers and Consolidation Include Only Legal Mergers and Consolidation.* For the purposes of this paragraph (c) of this section, a merger or consolidation does not include transactions in which an insured depository institution either directly or indirectly acquires the assets of, or assumes liability to pay any deposits made in, any other insured depository institution, but there is not a legal merger or consolidation of the two insured depository institutions.

(11) *Use of Credits.*—

(i) The FDIC shall apply assessment credits awarded under this paragraph (c) to an institution's deposit insurance assessments, as calculated under § 327.9, only for assessment periods in which the reserve ratio of the DIF exceeds 1.40 percent.

(ii) The FDIC shall apply assessment credits to reduce an institution's quarterly deposit insurance assessments by the lesser of each institution's remaining credits or 0.5 basis points multiplied by the institution's deposit insurance assessment base in the assessment period. The assessment credit applied to each institution's deposit insurance assessment for any assessment period shall not exceed the institution's total deposit insurance assessment for that assessment period.

(iii) Any credits remaining 12 assessment periods after the FDIC begins to apply the assessment credits under this section will be applied to the full amount of the assessment due for the following assessment period, and subsequent assessment periods, as

determined under § 327.9, until the credits are exhausted.

(iv) The amount of credits applied each quarter will not be recalculated as a result of amendments to the quarterly Reports of Condition and Income or the quarterly Reports of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks pertaining to any quarter in which credits have been applied.

(d) *Request for Review and Appeals of Assessment CreditsÐ*

(1) An institution that disagrees with the basis for its assessment credits, or the Corporation's computation of its assessments credits, under paragraph (c) of this section and seeks to change it must submit a written request for review and any supporting documentation to the FDIC's Director of the Division of Finance.

(2) *Timing.* Any request for review under this paragraph must:

(i) Be submitted within 30 days from

(A) The initial notice provided by the FDIC to the insured depository institution under paragraph (c)(6) of this section stating the FDIC's preliminary estimate of an eligible institution's assessment credit and the manner in which the assessment credit was calculated; or

(B) Any updated notice provided by the FDIC to the insured depository institution under paragraph (c)(6) of this section.

(ii) Any requests submitted after the deadline in paragraph (d)(2)(i) of this section will be considered untimely filed and the institution will be subsequently barred from submitting a request for review of its assessment credit.

(3) *Process of Review.*

(i) Upon receipt of a request for review, the FDIC would temporarily freeze the amount of the assessment credit being reviewed until a final determination is made by the Corporation.

(ii) The FDIC may request, as part of its review, additional information from the insured depository institution involved in the request and any such information must be submitted to the FDIC within 21 days of the FDIC's request.

(iii) The FDIC's Director of the Division of Finance, or his or her designee, will notify the requesting institution of his or her determination of whether a change is warranted within the latter of the following timeframes:

(A) 60 days of receipt by the FDIC of the request for review; or

(B) If additional information had been requested from the FDIC, within 60 days of receipt of any such additional information.

(4) *Appeal.* If the requesting institution disagrees with the final determination from the Director of the Division of Finance, that institution may appeal its assessment credit determination to the FDIC's Assessment Appeals Committee within 30 days from the date of the Director's written determination. Notice of the procedures applicable to an appeal before the Assessment Appeals Committee will be included in the Director's written determination.

(5) *Adjustments to Assessment Credits.* Once the Director of the Division of Finance, or the Assessment Appeals Committee, as appropriate, has notified the requesting bank of its final determination, then the FDIC will make appropriate adjustments to assessment credit amounts consistent with that determination. Adjustments to an insured depository institution's assessment credit amounts will not be applied retroactively to reduce or increase the quarterly deposit insurance assessment for a prior assessment period.

■ 4. In § 327.35 revise paragraph (a) to read as follows:

§ 327.35 Application of credits.

(a) Subject to the limitations in paragraph (b) of this section, the amount of an eligible insured depository institution's one-time credit shall be applied to the maximum extent allowable by law against that institution's quarterly assessment payment under subpart A of this part, after applying assessment credits awarded under § 327.11(c), until the institution's credit is exhausted.

* * * * *

By order of the Board of Directors.

Dated at Washington, DC, this 22nd day of October, 2015.

Federal Deposit Insurance Corporation.

Robert Feldman,

Executive Secretary.

[FR Doc. 2015–27287 Filed 11–5–15; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–132075–14]

RIN 1545–BM49

Extension of Time To File Certain Information Returns; Extension of Comment Period

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: This document extends the comment period for a notice of proposed rulemaking (REG–132075–14) that was published in the **Federal Register** on Thursday, August 13, 2015. The proposed regulations relate to extensions of time to file information returns on forms in the W–2 series (except Form W–2G).

DATES: Written or electronic comments and requests for a public hearing for the notice of proposed rulemaking published on August 13, 2015 (80 FR 48472), is extended to January 11, 2016.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG–132075–14), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–132075–14), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically, via the Federal eRulemaking Portal at *http://www.regulations.gov* (indicate IRS and REG–132075–14).

FOR FURTHER INFORMATION CONTACT: Jonathan R. Black at (202) 317–6845 (not a toll free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking that appeared in the **Federal Register** on Thursday, August 13, 2015 (80 FR 48472) announced that written and electronic comments and requests for a public hearing must be received by November 12, 2015. In order to provide the public with a sufficient opportunity to submit comments, the due date to receive electronic comments and requests for a public hearing has been extended to Monday, January 11, 2016.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2015–28279 Filed 11–5–15; 8:45 am]

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DEPARTMENT OF VETERAN AFFAIRS

38 CFR Part 74

RIN 2900–A063

VA Veteran-Owned Small Business (VOSB) Verification Guidelines

AGENCY: Department of Veteran Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its regulations governing the VA Veteran-Owned Small Business (VOSB) Verification Program. VA seeks to find an appropriate balance between preventing fraud in the Veterans First Contracting Program and providing a process that would make it easier for more VOSBs to become verified. The Verification Program has been the subject of reports from both the Government Accountability Office (GAO) and VA's Office of Inspector General stating that despite VA's Verification Program, fraud still exists in the Veterans First Contracting Program. Some stakeholder feedback has been that the current regulations at 38 CFR part 74 are too open to interpretation and are unnecessarily more rigorous than similar certification programs run by the Small Business Administration (SBA). This proposed rule would clarify the eligibility requirements for businesses to obtain ''verified'' status, add and revise definitions, reorder requirements, redefine the definition of ''control'', and explain examination procedure and review processes. This proposed rule would additionally implement new changes—references to community property restrictions, ''unconditional'' ownership, day-to-day requirements, and full-time requirements would be removed or revised and limited in scope; an exception for majority, supermajority, unanimous, or other voting provisions for extraordinary business decisions would be added.

DATES: Comments must be received by VA on or before January 5, 2016.

ADDRESSES: Written comments may be submitted through *www.Regulations.gov;* by mail or hand-delivery to Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Ave. NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to ''RIN 2900–AO63—VA Veteran-Owned Small Business (VOSB) Verification Guidelines''. Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Tom Leney, Executive Director, Office of Small and Disadvantaged Utilization (00VE), Department of Veterans Affairs, 810 Vermont Ave. NW., Washington, DC 20420, (202) 461–4300. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: An Advanced Notice of Proposed Rulemaking was provided with a 60-day comment period which ended on July 12, 2013. We received comments from 39 commenters; the issues raised by these comments have been considered in drafting this proposed rule. We thank all commenters for their participation in this process. The bases for the proposed amendments are as follows.

Within § 74.1, VA proposes to create two new terms and amend or remove several definitions. New terms; ''daily business operations'' and ''Permanent caregiver'' would be added. The term ''daily business operations'' would replace ''Day-to-day management'' and ''day-to-day operations'' both of which would be removed; these definitions would be merged in order to simplify amendments made to § 74.4 while ensuring statutory requirements are still enforced/imposed. In addition, Permanent caregiver would be incorporated into § 74.1 whereas previously the concept and terminology was referenced in the regulation, most clearly at § 74.4(g)(1), but not defined. The term would be changed to permanent caregiver and references to personal caregiver would be removed. This amendment would create a definition which would account for definitions of similar and related terms found in 13 CFR 125.8(c), 13 CFR 125.8(d), 38 CFR 3.340(b), and 38 CFR 71.30. This change is intended to take multiple requirements, found throughout regulation, and synthesize them into a single cohesive definition. For purposes of this Part, a requirement that the applicant provide an explanatory statement which states the nexus between the veteran's disability and the need for the permanent caregiver to manage the concern would be added to assist in program administration.

The following terms would be amended:

The term Center for Veterans Enterprise would be changed to revise Center for Verification and Evaluation (CVE) to reflect the name change effectuated at 78 FR 59861, September 30, 2013. The definition of CVE would be further amended to reflect the change to the functions of this office.

Joint venture would be amended to contain project and time restrictions utilized by other set-aside programs. VA has also added language to clearly address the current policy by indicating that at least one venturer must be a Veteran Owned Small Business (VOSB).

The definition of Office of Small and Disadvantaged Business Utilization would be amended to more accurately convey the role fulfilled by this office with respect to VOSB matters.

Participant would be amended to emphasize CVE's role in verifying status.

Primary industry classification would be amended to make a technical change to use the acronym NAICS as it had already been spelled out and properly noted in a parenthetical earlier in the definition.

Principal place of business would be amended to make a technical change, specifically the term ''day-to-day operation'' would be removed and replaced by ''daily business operations'' in accordance with the amended term from earlier in the definitions section.

Service-disabled veteran would be amended as the current definition has led to confusion regarding the documentation necessary to establish a service-connected disability. This change would also help increase program efficiency by specifically referencing BIRLS, the system that allows CVE to quickly and accurately determine veteran status.

Service-disabled veteran-owned small business concern would be amended to remove reference to Reservists or members of the National Guard. This reference is appropriately addressed by the amended definition of Veteran. The word spouse would be removed in the first sentence and the word ''the'' would be added before ''permanent caregiver''. This change would clarify for the public and potential participants the situations under which a permanent caregiver, previously referred to as a personal caregiver or spouse, would be able to maintain VOSB eligibility on behalf of a veteran. In the amended regulation, the requirements one must meet to serve as a permanent caregiver would be clearly defined. In order to avoid fraud, waste and abuse any spouse seeking to stand in for a veteran with permanent

and severe disability would have to meet these same requirements. Therefore, the reference to spouse, separately from permanent caregiver, would be redundant and potentially confusing. Due to the use of the term ''veteran'' as opposed to ''veteran or service-disabled veteran'' throughout the amended regulation, a new last sentence would be added to clearly state that this change did not alter the requirements for an SDVOSB.

Small business concern would be amended to make a technical change removing the word ''is'' simply for clarity.

Surviving Spouse would be amended to make a technical change, specifically the Veterans Benefits Administration would be abbreviated as VBA.

The definition for unconditional ownership would be removed; the concept of ownership as required for this program would be addressed only in § 74.3(b) to avoid any conflict in the interpretation of the meaning.

Verification eligibility period would be amended to reflect the increased period for eligibility—which was changed from 12 months to 2 years; this amendment was established via 77 FR 38181, June 27, 2012. Additionally a technical change would amend the reference to Center for Veterans Enterprise by replacing it with the abbreviation CVE. A final technical change would replace the word ''year'' with ''eligibility period'' to agree with the change in the first sentence.

Veteran would be amended to add a reference to VBA. This revised definition is meant to be inclusive of all persons who served on active duty and were discharged or released under conditions other than dishonorable. Historically the program has had an issue wherein applicants who did in fact qualify as veterans under the statutory definition, did not meet the standards outlined in § 74.1. This change is not intended to create a new class of veteran, but rather to clarify that those who are eligible under the applicable statutes will be found eligible for participation in this program.

Veterans Affairs Acquisition Regulation is amended to remove Veterans Affairs and refer to VA as this is previously defined within the section.

Section 74.2 would be amended by revising paragraphs (a)–(e) and adding new paragraphs (f) and (g). In both 2010 and 2012, GAO published reports tasking VA with reducing potential instances of fraud, waste and abuse. VA has found in its administration of the verification program that the use of the procedures identified in § 74.2(e) best protects VA acquisition integrity and diminishes ongoing exposure to fraud, waste and abuse. Therefore, for such limited situations as identified in § 74.2, and only in these limited instances, VA finds that immediate removal from public listing is warranted in order to protect the integrity of VA procurement. Accordingly, the amendments to § 74.2 would serve to more comprehensively outline the circumstances under which a participant would be found ineligible for the VOSB Verification program

Section 74.2(a) would be amended to add the clause ''submitted required supplemental documentation at *http://www.VetBiz.gov,*'' to clearly explicate the key steps necessary for an application and verification. Additionally, a technical change would be made to use the abbreviated form ''CVE'' for consistency.

Section 74.2 (b) would be amended to support the current policy use of good character to address the potential impact of criminal activity on eligibility and thus to better protect the government from fraud, waste and abuse. The title would be amended to reference the System for Award Management (SAM), which has replaced the Excluded Parties List System. Additionally, the language of the first sentence would be amended to address the impact of 38 U.S.C. 8127(g)(3), which now provides VA authority to exclude all principals in the business concern. Accordingly, the language of § 74.2 would be amended to provide notice that the debarment of any individual holding an ownership and control interest in the concern will impact the concern's eligibility.

Section 74.2(c) would be amended by adding the phrase ''false statements or information'' to reference the title and provide further clarification on the eligibility requirements. The removal provision would be additionally reworded to clarify the current policy interpretation that removal is immediate. Finally a technical change would remove ''the'' before CVE in the last sentence.

Section 74.2(d) would be amended by including tax liens and unresolved debts owed to various governmental entities outside of the Federal government as financial obligations that would disqualify an applicant for inclusion in the Vetbiz VIP database. The title would be additionally amended to reflect this change.

Section 74.2(e) would be amended to clarify the consequences of SBA protest decisions and other negative findings. ''Other negative findings'' was additionally clarified by specifically referencing status protest decisions pursuant to 48 CFR 819.307. The title of this section would be accordingly amended to clarify this section is not limited to SBA decisions. In order to properly effectuate the provisions of the amended 48 CFR 819.307, § 74.2(e) would be amended to allow for immediate removal. The final sentence would be amended to take into account ''other negative findings.''

Section 74.2(f) would be added to better effectuate the licensure requirement previously found in § 74.21(9). Through administration of the program, VA has determined that continued inclusion of concerns who fail to obtain and keep current required licenses creates a significant risk to the procurement process. Therefore, immediate removal from the VetBiz VIP database is warranted to protect the agency from fraud, waste and abuse.

Section 74.2(g) would be added to specifically reference SAM registration. SAM is a consolidated listing of previous databases and was not in existence at the time the original regulation was created and therefore was not referenced. Registration through SAM is required by 48 CFR 4.1200 (supplemented by 48 CFR 804.1102).

Section 74.3(a) would be amended to simplify the title in order to avoid the potential for confusion. A technical change would remove the reference service-disabled Veteran. Reference to both veterans and service-disabled veterans in the regulation has proven to cause confusion for some applicants. By referencing only veterans, and making a change to the definition of service-disabled veteran owned small business, that confusion would be eliminated. The reference to employee stock ownership plans (ESOPs) would also be removed. Through years of program administration it has become clear that this exception does not fit within the verification program. ESOPs have changed in ways making evaluation very difficult. It is not clear how this exception benefits the veteran owner. Concerns having ESOPs could still be verified, so long as they meet all of the ownership requirements set forth in the regulation.

Section 74.3(b) would be amended to directly address the concerns of VA in balancing commercially reasonable business practices against procurement integrity. Section 74.3(b) as it is currently written is considered by many in the veteran community to be unduly burdensome. VA considered these concerns and addressed them by proposing to limit the scope of unconditional ownership, accepting commercially reasonable conditions and excluding only those that create a significant risk of fraud, waste and

abuse. The new language would outline the concept of commercially reasonable business practices and how they will be evaluated by the program. The exception for conditions after death or incapacity would remain unchanged. Section 74.3(b)(1) would be added to explain the process by which CVE will evaluate the commercial reasonability of conditions. This would be done on a case-by-case basis. Section 74.3(b)(2) would be added separately as the scenario addressed, regarding absence of fully vested interests, relates to a significant risk for fraud, waste and abuse, which would therefore bespecifically exempted from the commercial reasonability analysis described in § 74.3(b)(1).

Section 74.3(c) would be amended by numerous technical changes. Specifically, subparagraphs (1), (2), and (3) would be removed from paragraph (b) and redesignated in new paragraph (c). Additional technical change to new paragraph (c) would remove references to ''unconditional'' as the requirements of this paragraph apply to all aspects of ownership. The reference to service-disabled veteran would be removed to conform with changes outlined in the explanation of § 74.3(a). Language would be added to paragraphs 74.3(c) (2) and (3) to align with a similar statement in paragraph (1) expressing how ownership must be demonstrated.

Section 74.3(c) would be redesignated as § 74.3(d) to account for new § 74.3(c) having been added. A technical change would remove the reference to service-disabled veteran to conform with changes outlined in the explanation of § 74.3(a).

Section 74.3(d) would be redesignated as § 74.3(e) to account for addition of new § 74.3(c). A technical change would remove the reference to service-disabled veteran to conform with changes outlined in the explanation of § 74.3(a). The clause relating to joint venture profit distribution would be removed from this section. This requirement would be now addressed in § 74.5. Section 74.4(d)(5) (redesignated § 74.4(e)(4)) would be amended to change ''should'' to ''must'' in order to create an enforceable requirement.

Section 74.3(e) would be redesignated as § 74.3(f) to account for addition of new § 74.3(c). A technical change would remove the reference to service-disabled veteran to conform with changes outlined in the explanation of § 74.3(a). Section 74.3(e)(1) would be amended by a technical change to replace ''application'' with ''VA Form 0877'' in order to clarify the requirement and conform language to the rest of the regulation. Section 74.3(e)(1) would be changed to add a 30-day time period for submission of new application after a change in ownership. This change would provide the agency the ability to definitively and accurately track changes of ownership. By adding a time period for new application, the program would be better able to comply with its statutory mandate of verifying that all concerns listed in the VIP Database meet the ownership and control requirement of the regulation.

Section 74.3(e)(3) would be amended by a technical change to replace ''application'' with ''VA Form 0877'' in order to clarify the requirement and conform language to the rest of the regulation.

Section 74.3(e)(4) would be amended to add a reference to § 74.14 to demonstrate the potential impact of change of ownership on the eligibility period.

Section 74.3(f) would be removed in its entirety. In administering the program, this requirement was found to be unduly burdensome on veterans. CVE has also found that implementation of this provision does not significantly reduce the risk of fraud, waste and abuse in the program.

Section 74.4(a) would be amended to align with the changes made to definitions in § 74.1. The term ''day-to-day management'' would be removed as described above, and this would require the language of § 74.4(a) to be revised. The second sentence is moved from § 74.4(b) for organizational purposes and clarity.

Section 74.4(b) would be amended to align with the changes made to definitions in § 74.1. The term ''day-to-day management'' would be removed as descried above, and this would require the language of § 74.4(b) to be revised. The last sentence would be amended to add a reference to § 74.4(j)(2) in order to properly identify the paragraph which establishes this requirement.

Section 74.4(c)(1) would be amended by technical change to remove ''or service-disabled veterans'' to eliminate confusion. Veteran classification issues are already addressed in § 74.1 as described above. The second and third sentences would be edited to clarify that the requirements apply only to Veteran owners, as opposed to non-Veteran owners of the concern. Section 74.4(c)(2) would be amended by technical change to redesingatelist as (c)(3). Section 74.4(c)(3) would be amended by technical change to be listed as (c)(2). The new organization would more logically group related concepts. Section 74.4(c)(4) would be amended by a technical change to be listed as § 74.4(d). This amendment would make it clear that this requirement applies to all aspects of control, not just those detailed in § 74.4(c). An additional technical change would amend the reference to paragraph (f) to paragraph (h) to correspond with redesignating of sections described below.

Section 74.4(e) would be amended and reorganized. VA would reorganize this provision, as well as following paragraphs of § 74.4 to clarify that there are certain control requirements that apply to all business entities, while others apply to specific business types (*e.g.* Corporation, LLC, Partnership). This new organization would clearly lay out the generally applicable standards in paragraph (e) and then move to the specific requirements for different business types in the following paragraphs. In the current version of the regulation, these general and specific requirements exist, but are not laid out in a logical and clear manner.

A new provision would be added in at § 74.4(e) in order to describe the general control requirements outlined in the explanation above. A reference to ''extraordinary business decisions'' would be added at § 74.4(e)(1) and (3) to clarify existing program policy. This exception would protect the minority owners of firms thereby encouraging investment and participation in veteran owned businesses. Section 74.4(d) would be redesignated as § 74.4(f) to account for addition of new § 74.4(d) and § 74.4(e). Language would be added to refer to § 74.4(e)(1) to assimilate the exception created therein. Section 74.4(e) would be redesignated as § 74.4(g) to account for addition of new § 74.4(d) and § 74.4(e). Language would be added to refer to § 74.4(e)(1) to assimilate the exception created therein. Section 74.4(f) would be redesignated as § 74.4(h) to account for the addition of new § 74.4(d) and § 74.4(e). Section 74.4(f) is would also be amended to account for the general requirements of 74.4(e) and to emphasize the specific criterion relating only to incorporations. Section 74.4(f) (new § 74.4(h) would also be amended to succinctly and clearly encapsulate the exception created in existing § 74.4(f)(1) (i), (ii), and (iii), and referenced in § 74.4(c)(4). The language ''at any time for any reason'' would be added to focus the provision on commercially reasonable business structures. VA intends these changes to simplify requirements relating to control and delete redundancies. Section 74.4(g) and its associated subparagraphs would be redesignated as § 74.4(i). It would be further amended by technical change to remove the word ''such'' from the

second sentence in order to clarify that these limitations apply to all non-Veterans. This change would help to guard against fraud. The term ''personal caregiver'' would be changed to ''permanent caregiver'' to be consistent with the definition added to § 74.1. Section 74.4(g)(3), redesignated as § 74.4(i)(3), would be amended to replace the word ''salary'' with ''compensation'' in order to be consistent. Additionally, in order to reflect current program policy, the word ''dividends'' would be replaced by the word ''distributions'' with regard to sources of compensation. This reference would be moved to directly follow the word ''compensation'' for clarity. Section 74.4(i) would be redesignated as § 74.4(j) with conforming and clarifying changes.

Section 74.5 would be revised to include joint ventures. The language would be reworded to clearly establish that 38 CFR part 74 does not supersede 13 CFR part 121 with respect to size determinations. A paragraph (b) would be added to specifically address eligibility of joint ventures. Subparagraph (b)(2) would be moved from its previous placement in 38 CFR 74.3(d)(2) for organization and to address all joint venture issues in one section. Additionally, the language would be edited in order to clarify that the VOSB entity, rather than the individual Veteran owner(s), must be entitled to the distribution. Subparagraphs (b)(1) and (b)(3) would be added to provide notice of the requirements outlined elsewhere in VA Regulation (819.7003).

Section 74.10 would be amended to remove reference to physical address for CVE. Addresses or methods for submission may change over time, and this change allows CVE to make reasonable and necessary adjustments without the need for amendment of the regulation.

Section 74.11 would be amended by a technical change to redesignate paragraphs (c)–(g) to account for addition of new paragraph (c). Additionally, ''Center for Veterans Enterprise'' would be changed to ''CVE'' in paragraph (a). Finally, ''[t]he CVE'' would be changed to ''CVE'' in paragraph (a).

Section 74.11(c) would be added to address the potential circumstances created if CVE does not receive all requested documentation. As a result of statutory changes, the program now must certify applicants prior to admission in the database. In order to comply with the statute, VA requests documentation to demonstrate eligibility. This paragraph would put the public on notice that failure to adequately respond to these document requests may render CVE unable to verify the eligibility of a concern and therefore may result in denial. The original § 74.11(c) would be redesignated as § 74.11(d) and would be amended by a technical change to insert a reference to the newly added paragraph (c). Additionally, the reference to paragraph (d) would be changed to paragraph (e) to account for redesignating. The term ''totality of circumstances'' would be added to clarify long standing CVE interpretation and procedure. References to § 74.11(b) and § 74.13(a) would be added to highlight all applicable exceptions. Finally, a last sentence would be added to clarify in the regulatory text longstanding VA policy that the applicant bears the burden of establishing VOSB status.

Section 74.11(d) would be redesignated as § 74.11(e). The third sentence would be removed as it refers to withdrawal or removal of verified status. This issue is addressed in 38 CFR 74.21, which specifically deals with how participants can exit the VetBiz VIP database. Therefore, the removal would help to eliminate redundancy and reduce the likelihood of confusion. Current § 74.11(e) would be redesignated as § 74.11(f), and § 74.11(f) would be redesignated as § 74.11(g).

The revised § 74.11(e) would consist of subparagraphs (1) and (2). Subparagraph (1) would continue to provide notice of the requirement for participants to provide notice to CVE of changed circumstances. Subparagraph (2) would specify that bankruptcy is a changed circumstance, and the section would include requirements to protect the agency through the bankruptcy process.

Current section 74.11(g) would be redesignated as § 74.11(h). A second sentence would be added to increase program efficiency by ensuring that applicants provide updated contact information. This would allow the program to use the most efficient methods to dispatch determinations and ensure that applicants will receive determinations in a timely manner.

Section 74.12 would be amended to expand the list of required documentation in order to provide notice of documentation that is routinely requested by CVE. This amended list would include documents previously referenced by § 74.20(b). While the documents would still be required for examination as described in § 74.20(b), they also are initially required for the application. As the application is a concern's first exposure with the process, VA finds this list would be more appropriately placed in this section to put the public on notice of the documentary requirements. Additionally, ''electronic form'' would be changed to ''VA Form 0877'' throughout for clarity. Similarly, ''attachments'' would be changed to ''supplemental documentation'' throughout. Finally, the last two sentences would be combined and slightly reworded for clarity.

Section 74.13(a) would be amended to modify the start of the relevant 30-day time period. This change would provide the agency the ability to definitively and accurately track the request for reconsideration proceedings. Additionally, this change would provide the agency the ability to control the regulatory time period and consistently apply the subsequent provisions of the paragraph. The instructions for submission of a request for reconsideration would be changed to indicate that all instructions for proper submission will be found in the denial decision. Addresses or methods for submission may change over time, and this change would allow CVE to make reasonable and necessary adjustments without the need for amendment of the regulation. A sentence stating that the applicant may submit additional or amended documentation would be added to clarify existing program policy. Finally, the last sentence would be removed due to redundancy with the first sentence of paragraph (b).

Section 74.13(d) would be amended to change ''or'' to ''and'' in the first sentence to accurately reflect the actions taken by CVE in these situations. Additionally, information regarding how an applicant can request a formal size determination from the SBA would be removed as individual business concerns cannot request formal size determinations. In an instance where CVE denies for size issues, CVE would request a formal size determination directly, and the company would be eligible to submit a request for reconsideration. A conforming amendment would be made to § 74.13(e). Section 74.13(g) would be amended to add a sentence to increase program efficiency by ensuring that applicants provide updated contact information. This would allow the program to use the most efficient methods to dispatch determinations and ensure that applicants will receive the determinations in a timely manner.

Section 74.14 would be amended to include notices of verified status cancellation in the list of determinations that trigger a waiting period before a concern may submit a new verification

application. This appears to have been an omission in the prior version of the regulation. Additionally, the waiting period would be expanded from 6 months to 12 months. The program has instituted several procedures to assist applicants to identify and address easily correctable issues that render the applicant ineligible. The class of notices listed in § 74.14 are generally issued to applicants with substantial issues causing ineligibility. The 12-month waiting period would ensure that applicants will be motivated to avail themselves of the resources provided by CVE and allow sufficient time for ineligible concerns to address significant issues. Additionally, this would increase the efficiency of the program by reducing the number of applications submitted by concerns that do not conform to the verification guidelines.

The current text of § 74.14, as amended, would be designated as § 74.14(a) and new provisions would be added in § 74.14(b) providing for immediate removal of ineligible participants from the VetBiz VIP verification database. VA only intends, to the extent practicable, to list as verified in the VetBiz VIP database concerns which currently meet verification requirements. This would serve the important purpose of assisting COs in the procurement process by ensuring the database only includes concerns that are eligible for award of set aside procurements.

Section 74.15(a) would be split into paragraphs (a), (b), and (c). A technical change would be made to what would be redesignated as § 74.15(a) to improve specificity. A change would be made to what would be redesignated as § 74.15(b) to require participants to inform CVE within 30 days of changes affecting eligibility, consistent with § 74.3(f)(1). A substantive change would be made to the list that would be redesignated as § 74.15(c), which would be expanded to include all situations in which the eligibility period may be shortened. Section 74.15(b) would be removed because it dealt with affiliation. Section 74.5 would state that the SBA will make determinations on affiliation. Therefore, any shortening of the eligibility period due to an affiliation determination would result from an SBA determination. This scenario would be addressed by § 74.2(e), and is referenced appropriately at what would be designated § 74.15(c). Finally, paragraphs (c), (d), and (e) would be redesignated as (d), (e) and (f) respectively.

Section 74.20(b) would be amended by minor technical changes in the first three sentences for simplicity and clarification. In the first sentence, the phrase, ''or parts of the program examination'' would be removed. In the second sentence, ''location'' would be changed to ''location(s).'' In the third sentence, the word ''[e]xaminers'' is changed to ''CVE.'' Section 74.12, ''[w]hat must a concern submit to apply for VetBiz VIP Verification Program,'' would fully address the required documentation necessary for verification and therefore the complete list would be removed from § 74.20 in order to avoid redundancy and confusion.

Section 74.21 would be extensively reordered for clarity and to conform with changes made to other sections of the regulatory text. Section 74.21(a) would be amended by a technical change to remove reference to the ''verified' status button'' in order to reflect the current graphical user interface of the VIP database. Additionally, ''Vendor Information Pages'' would be changed to ''VIP.'' Section 74.21(b) would include a technical edit, ''Vendor Information Pages'' changed to ''VIP.'' Section 74.21(c) would be added to reference the immediate removal provisions established by and clarified in § 74.2. Previous § 74.21(c) and associated subparagraphs would be redesignated as § 74.21(d) and associated subparagraphs. Additionally, reference to the '''verified' status button'' would be removed to reflect the current graphical user interface of the database. Section 74.21(c)(5) would be removed as involuntary exclusions would now be addressed in § 74.2. Section 74.21(c)(6) would be redesignated as § 74.21(d)(5) to account for deletion of (c)(5). Additionally, the phrase ''or its agents'' would be added to clarify who may request documents. Section 74.21(c)(7) would be redesignated as § 74.21(d)(6) to account for deletion of (c)(5). Section 74.21(c)(8) would be removed as the action addressed by that provision would now be addressed in § 74.2. Section 74.21(c)(9) would be removed as the provision would now be included in § 74.2 as a grounds for immediate removal. Section 74.21(c)(10) would be redesignated as § 74.21(d)(7). The term ''application'' would be removed as VA Form 0877 reflects current program requirements. 60 days would be changed to 30 days to conform with revised § 74.3(f)(1) of this part. Section 74.21(e) would be added as notice to the public that failure to report changed circumstances within 30 days is in and of itself good cause to initiate cancellation proceedings.

Section 74.22(a) would be amended to base the start of the relevant 30-day time period on the date on which CVE sent notice of proposed cancellation of verified status. This change would provide the agency the ability to definitively and accurately track the cancellation proceedings. Additionally, this change would provide the agency the ability to control the regulatory time period and consistently apply the subsequent provisions of the paragraph. section 74.22(e) would be amended by a technical change to replace ''Office of Small and Disadvantaged Business Utilization'' with ''OSDBU.''

Section 74.25 would be amended by a technical change to replace ''Department'' with ''VA.'' Additionally, the provision would be revised to expand the pool of individuals required to provide personally identifiable information.

Section 74.26 would be amended by technical change to reflect the amended title of § 74.12.

Section 74.27 would be amended to reword the first sentence to specify that all documents submitted to the program, not only those used to complete applications, will be stored electronically. Additionally, ''VetBiz Vendor Information Pages'' would be changed to ''CVE'' in order to clearly denote who will be in possession of the documents and responsible for their retention. The location reference would be removed due to the electronic nature of the records to be maintained by the program. The second sentence would be revised to indicate that any owner information provided will be compared to any available records. Finally, references to records management procedures to be followed and procedures governing data breaches would be added.

Section 74.28 would be amended to abbreviate references to VA and CVE.

Section 74.29 would be amended to refer to VA's records management procedures, which would govern, absent a timely written request from the Government Accountability Office.

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by this rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All VA guidance would be read to conform with the rule finally adopted if possible or, if not possible, such guidance would be superseded.

Paperwork Reduction Act

This proposed rule contains no provision constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This proposed rule would generally be small business neutral, as it would apply only to applying for verified status in the VetBiz.gov Vendor Information Pages (VIP) database. The proposed regulation would merely seek to clarify and streamline the existing rule and would add no additional burdens or restrictions on applicants or participants with regard to the VA VOSB Verification Program. The overall impact of the proposed rule would be of benefit to small businesses owned by veterans or service-disabled veterans. VA estimates the cost to an individual business to be less than $100.00 for 70–75 percent of the businesses seeking verification, and the average cost to the entire population of veterans seeking to become verified is less than $325.00 on average. On this basis, the Secretary certifies that the adoption of this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act. Therefore, under 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of §§ 603 and 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages, distributive impacts and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' which requires review by the Office of Management and Budget (OMB), as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

This proposed rule would affect the verification guidelines of veteran-owned small businesses, for which there is no Catalog of Federal Domestic Assistance program number.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Nabors II, Chief of Staff, Department of Veterans Affairs, approved this document on October 20, 2015, for publication.

List of Subjects in 38 CFR Part 74

Administrative practice and procedure, Privacy, Reporting and recordkeeping requirements, Small businesses, Veterans.

Dated: November 2, 2015.

Michael P. Shores,

Chief Impact Analyst, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons set forth in the preamble, we propose to amend 38 CFR part 74 as follows:

PART 74—VETERANS SMALL BUSINESS REGULATIONS

■ 1. The authority citation for Part 74 continues to read as follows:

Authority: 38 U.S.C. 501 and 513, unless otherwise noted.

■ 2. Revise § 74.1 to read as follows:

§ 74.1 What definitions are important for VetBiz Vendor Information Pages (VIP) Verification Program?

For the purpose of part 74, the following definitions apply.

Center for Verification and Evaluation (CVE) is an office within the U.S. Department of Veterans Affairs (VA) and is a subdivision of VA's Office of Small and Disadvantaged Business Utilization. CVE receives and reviews all applications for eligibility under this part and maintains the VIP database. CVE assists VA contracting offices to identify veteran-owned small businesses and communicates with the Small Business Administration (SBA) with regard to small business status.

Daily Business Operations are, at a minimum, the marketing, production, sales, and administrative functions of the firm, as well as, the supervision of the executive team, the implementation of sound policies and the setting of the strategic direction of the firm.

Days are calendar days. In computing any period of time described in part 74, the day from which the period begins to run is not counted, and when the last day of the period is a Saturday, Sunday, or Federal holiday, the period extends to the next day that is not a Saturday, Sunday, or Federal holiday. Similarly, in circumstances where CVE is closed for all or part of the last day, the period extends to the next day on which the agency is open.

Eligible individual means a veteran, service-disabled veteran, or surviving spouse, as defined in this section.

Immediate family member means father, mother, husband, wife, son, daughter, brother, sister, grandfather, grandmother, grandson, granddaughter, father-in-law, and mother-in-law.

Joint venture is an association of two or more small business concerns to engage in and carry out no more than three specific or limited-purpose business ventures for joint profit over a two year period, for which purpose they

combine their efforts, property, money, skill, or knowledge, but not on a continuing or permanent basis for conducting business generally. A joint venture must be comprised of at least one veteran owned small business. For VA contracts a joint venture must be in the form of a separate legal entity.

Negative control includes, but is not limited to, instances where a minority shareholder has the ability, under the concern's chapter, by-laws, or shareholder's agreement, to prevent a quorum or otherwise block action by the board of directors or shareholders

Non-veteran means any individual who does not claim veteran status, or upon whose status an applicant or participant does not rely in qualifying for VetBiz Vendor Information Pages (VIP) Verification Program participation.

Office of Small and Disadvantaged Business Utilization (*OSDBU*) is the office within VA that establishes and monitors small business program goals at the prime and subcontract levels. OSDBU works with VA Acquisitions to ensure the creation and expansion of small businesses opportunities by promoting the use of set-aside contracting vehicles within VA procurement. OSDBU connects and enables veterans to gain access to these federal procurement opportunities. The Executive Director, OSDBU, is the VA liaison with the SBA. Information copies of correspondence sent to the SBA seeking a certificate of competency determination must be concurrently provided to the Director, OSDBU. Before appealing a certificate of competency, the Head of Contracting Activity must seek concurrence from the Director, OSDBU.

Participant means a veteran-owned small business concern which CVE has ''verified'' and deemed eligible to participate in VA's veteran-owned small business program.

Permanent caregiver is the spouse, or an individual, 18 years of age or older, who is legally designated, in writing, to undertake responsibility for managing the well-being of the service-disabled veteran with a permanent and severe disability, as determined by VA's Veterans Benefits Administration (VBA), to include housing, health and safety. A permanent caregiver may, but does not need to, reside in the same household as the service-disabled veteran with a permanent and severe disability. The applicant or participant must demonstrate that but for the permanent and severe disability the veteran would meet the requirements of this part. There may be no more than one permanent caregiver per service-disabled veteran with a permanent and severe disability. To be eligible for VetBiz VIP Verification, the applicant must provide the following:

(1) Appointment of the Permanent Caregiver. A permanent caregiver must be formally appointed. This can be accomplished by: (i) Order of a court of competent jurisdiction; (ii) designation of the VA, National Caregiver Support Program, as the Primary Family Caregiver of a veteran participating in the Program of Comprehensive Assistance for Family Caregivers (this designation is subject to the Veteran and the caregiver meeting other specific criteria as established by Public Law 111–163 and the Secretary and may be revoked if the eligibility criteria do not continue to be met); or (iii) a legal designation which clearly states that the permanent caregiver will undertake responsibility for managing the well-being of the service-disabled veteran.

(2) Determination of Disability. A written determination from VBA that the veteran has a permanent and total service-connected disability as set forth in 38 CFR 3.340.

(3) Explanatory Statement. A written statement that must include: (i) The rationale for the appointment of the permanent caregiver; (ii) an explanation of how the appointment contributes to the veteran's well-being; (iii) an explanation of why the permanent caregiver is needed to manage the applicant concern (including how the permanent caregiver is actually representing the veteran's interests in controlling/running the concern); and (iv) the veteran's consent to the appointment of the permanent caregiver.

Note to Definition of Permanent Caregiver: In the case of a service-disabled veteran with a permanent and severe disability lacking legal capacity, the permanent caregiver shall be a parent, guardian, or person having legal custody.

Primary industry classification means the six-digit North American Industry Classification System (NAICS) code designation which best describes the primary business activity of the participant. The NAICS code designations are described in the NAICS Manual published by the U.S. Office of Management and Budget.

Principal place of business means the business location where the individuals who manage the concern's daily business operations spend most working hours and where top management's current business records are kept. If the office from which management is directed and where the current business records are kept are in different locations, CVE will determine the principal place of business for program purposes.

Same or similar line of business means business activities within the same three-digit ''Major Group'' of the NAICS Manual as the primary industry classification of the applicant or participant. The phrase ''same business area'' is synonymous with this definition.

Service-disabled veteran is a veteran who possesses a service-connected disability rating between 0 and 100 percent. For the purposes of VA's veteran-owned small business program the service-connected disability can be established by either registration in the Beneficiary Identification and Records Locator Subsystem (BIRLS) maintained by the VBA, a disability rating letter issued by VA, or a disability determination from the Department of Defense.

Service-disabled veteran-owned small business concern (SDVOSB) is a business not less than 51 percent of which is owned by one or more service-disabled veterans, or in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; the management and daily business operations of which are controlled by one or more service-disabled veterans, or in the case of a veteran with a permanent and severe disability, the permanent caregiver of such veteran. In addition, some businesses may be owned and operated by an eligible surviving spouse. Ownership and control by a veteran, as opposed to a service-disabled veteran, will not meet the SDVOSB requirements set forth in this Part.

Small business concern—CVE applies the small business concern definition established by 48 CFR 2.101.

Surviving spouse is any individual identified as such by VA's VBA and listed in its database of veterans and family members. To be eligible for VetBiz VIP Verification, the following conditions must apply:

(1) If the death of the veteran causes the small business concern to be less than 51 percent owned by one or more veterans, the surviving spouse of such veteran who acquires ownership rights in such small business shall, for the period described in paragraph (2) of this definition, be treated as if the surviving spouse were that veteran for the purpose of maintaining the status of the small business concern as a service-disabled veteran-owned small business.

(2) The period referred to in paragraph (1) of this definition is the period beginning on the date on which

the veteran dies and ending on the earliest of the following dates:

(i) The date on which the surviving spouse remarries;

(ii) The date on which the surviving spouse relinquishes an ownership interest in the small business concern;

(iii) The date that is 10 years after the date of the veteran's death; or

(iv) The date on which the business concern is no longer small under Federal small business size standards.

(3) The veteran must have had a 100 percent service-connected disability or died as a direct result of a service-connected disability.

Note to Definition of Surviving Spouse: For program eligibility purposes, the surviving spouse has the same rights and entitlements of the service-disabled veteran who transferred ownership upon his or her death.

VA is the U.S. Department of Veterans Affairs.

Vendor Information Pages (VIP) is a database of businesses eligible to participate in VA's Veteran-owned Small Business Program. The online database may be accessed at no charge via the Internet at *http://www.VetBiz.gov.*

Verification eligibility period is a 2-year period that begins on the date CVE issues its Notice of Verified Status Approval letter establishing ''verified'' status. The participant must submit a new application for each eligibility period to continue eligibility.

VetBiz.gov (VetBiz) is a Web portal VA maintains at *http://www.VetBiz.gov.* It hosts the Vendor Information Pages database.

Veteran has the meaning given the term in section 101(2) of Title 38, United States Code, as interpreted through Title 38 of the CFR. In addition, any person having a determination of veteran status from VBA, and who was discharged or released under conditions other than dishonorable will be deemed to be a veteran for the purposes of this program.

Veteran-owned small business concern (VOSB) is a small business concern that is not less than 51 percent owned by one or more veterans, or in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; the management and business operations of which are controlled by one or more veterans and qualifies as ''small'' for Federal business size standard purposes. All service-disabled veteran-owned small business concerns (SDVOSBs) are also, by definition, veteran-owned small business concerns. When used in these guidelines, the term ''VOSB'' includes SDVOSBs.

Veterans Affairs Acquisition Regulation (VAAR) is the set of rules that specifically govern requirements exclusive to VA prime and subcontracting actions. The VAAR is chapter 8 of title 48, Code of Federal Regulations, and supplements the Federal Acquisition Regulation (FAR), which contains guidance applicable to most Federal agencies.

■ 3. Revise § 74.2 to read as follows:

§ 74.2 What are the eligibility requirements a concern must meet for VetBiz Vendor Information Pages (VIP) Verification Program?

(a) *Ownership and control.* A small business concern must be owned and controlled by one or more eligible veterans, service-disabled veterans or surviving spouses, have completed the online VIP database forms, submitted required supplemental documentation at *http://www.VetBiz.gov,* and have been examined by VA's CVE. Such businesses appear in the VIP database as ''verified''.

(b) *Good character and exclusions in System for Award Management (SAM).* Individuals having an ownership or control interest in VetBiz verified businesses must have good character. Debarred or suspended concerns or concerns owned or controlled by debarred or suspended persons are ineligible for VetBiz VIP Verification. Concerns owned or controlled by a person(s) who is currently incarcerated, or on parole or probation (pursuant to a pre-trial diversion or following conviction for a felony or any crime involving business integrity) are ineligible for VetBiz VIP Verification. Concerns owned or controlled by a person(s) who is formally accused of a crime involving business integrity are ineligible for VetBiz VIP Verification. If, after verifying a participant's eligibility, the person(s) controlling the participant is found to lack good character, CVE will remove the participant from the VIP database immediately, notwithstanding the provisions found in § 74.22 of this part.

(c) *False statements.* If, during the processing of an application, CVE determines, by a preponderance of the evidence standard (in keeping with other administrative actions), that an applicant has knowingly submitted false information, regardless of whether correct information would cause CVE to deny the application, and regardless of whether correct information was given to CVE in accompanying documents, CVE will deny the application. If, after verifying the participant's eligibility, CVE discovers that false statements or information has been submitted by a firm, CVE will remove the participant from the VetBiz VIP database immediately, notwithstanding the provisions of § 74.22 of this part. Whenever CVE determines that the applicant submitted false information, the matter will be referred to the Office of Inspector General for review. In addition, CVE will request that debarment proceedings be initiated by the Department.

(d) *Financial obligations.* Neither a firm nor any of its eligible individuals that fails to pay significant financial obligations, including unresolved tax liens and defaults on Federal loans or State or other government assisted financing, owed to the Federal government, the District of Columbia or any state, district, or territorial government of the United States, is eligible for VetBiz VIP Verification.

(e) *Protest Decisions or other negative findings.* Any firm verified in the VetBiz VIP database that is found to be ineligible by a SDVOSB/VOSB Status Protest decision will be immediately removed from the VetBiz VIP database, notwithstanding the provisions of § 74.22 of this part. Any firm verified in the VetBiz VIP database that is found to be ineligible due to a U.S. Small Business Administration (SBA) protest decision or other negative finding may be immediately removed from the VetBiz VIP database, notwithstanding the provisions of § 74.22 of this part. Until such time as CVE receives official notification that the firm has proven that it has successfully overcome the grounds for the determination, that the decision is overturned on appeal, or the firm applies for and receives verified status from CVE, the firm will not be eligible to participate in the 38 U.S.C. 8127 program.

(f) *Permits, licenses and state charters.* A concern must obtain and keep current any and all permits, licenses, and charters required to perform contracts sought by the concern. If CVE determines that an applicant fails to meet this requirement CVE will deny the application. If after verifying the participant's eligibility CVE discovers that the participant no longer satisfies this requirement, CVE will remove the participant from the VetBiz VIP database immediately, notwithstanding the provisions of § 74.22 of this part.

(g) *System for Award Management registration.* All applicants for VetBiz VIP Verification must be registered in SAM at *http://www.sam.gov,* or its successor prior to application submission.

■ 4. Revise § 74.3 to read as follows:

§ 74.3 Who does the Center for Verification and Evaluation (CVE) consider to own a veteran-owned small business?

An applicant or participant must be at least 51 percent directly and unconditionally owned by one or more veterans.

(a) *Direct ownership.* Ownership by one or more veterans must be direct ownership. An applicant or participant owned principally by another business entity that is in turn owned by one or more veterans does not meet this requirement; however, ownership by a trust, such as a living trust, may be treated as the functional equivalent of ownership by a veteran where the trust is revocable, and the veteran is the grantor, a trustee, and the sole current beneficiary of the trust.

(b) *Unconditional ownership.* Ownership must not be subject to prohibited conditions which cause or potentially cause ownership benefits to go to another (other than after death or incapacity).

(1) CVE will analyze conditions on ownership on a case-by-case basis. A condition(s) which is determined to align with commercially reasonable business practices will not be considered a prohibited condition. For purposes of determining commercial reasonability CVE will consider factors, including but not limited to, general use of similar conditions by concerns within the same or similar line of business and uniform applicability of the condition(s).

(2) Notwithstanding paragraph (b)(1) of this section, a veteran's ownership interest must be fully vested with immediate entitlement to all associated benefits.

(c) CVE will evaluate ownership according to the following criteria for specific types of small business concerns.

(1) *Ownership of a partnership.* In the case of a concern that is a partnership, at least 51 percent of each class of partnership interest must be owned by one or more veterans. The ownership must be reflected in the concern's partnership agreement.

(2) *Ownership of a limited liability company.* In the case of a concern that is a limited liability company, at least 51 percent of each class of member interest must be owned by one or more veterans. The membership interests must be reflected in the concern's operating agreement.

(3) *Ownership of a corporation.* In the case of a concern that is a corporation, at least 51 percent of each class of voting stock outstanding and 51 percent of the aggregate of all stock outstanding must be owned by one or more veterans. The ownership interests must be reflected in the concern's stock certificates and stock ledger.

(d) *Stock options' effect on ownership.* In determining ownership, CVE will disregard any unexercised stock options or similar agreements held by veterans. However, any unexercised stock options or similar agreements (including rights to convert non-voting stock or debentures into voting stock) held by non-veterans will be treated as exercised, except for any ownership interests that are held by investment companies licensed under Part 107 of title 13, Code of Federal Regulations.

(e) *Profits and distributions.* One or more veterans must be entitled to receive:

(1) At least 51 percent of the annual distribution of profits paid to the owners of a corporate, partnership, or LLC applicant or participant;

(2) 100 percent of the value of each share of stock owned by them in the event that the stock is sold; and

(3) At least 51 percent of the retained earnings of the concern and 100 percent of the unencumbered value of each share of stock owned in the event of dissolution of the corporation, partnership, or LLC.

(4) An eligible individual's ability to share in the profits of the concern must be commensurate with the extent of his/her ownership interest in that concern.

(f) *Change of ownership.*

(1) A participant may remain eligible after a change in its ownership or business structure, so long as one or more veterans own and control it after the change. The participant must file an updated VA Form 0877 and supporting documentation identifying the new veteran owners or the new business interest within 30 days of the change.

(2) Any participant that is performing contracts and desires to substitute one veteran owner for another shall submit a proposed novation agreement and supporting documentation in accordance with FAR Subpart 42.12 to the contracting officer prior to the substitution or change of ownership for approval.

(3) Where the transfer results from the death or incapacity due to a serious, long-term illness or injury of an eligible principal, prior approval is not required, but the concern must file an updated VA Form 0877 with contracting officer and CVE within 60 days of the change. Existing contracts may be performed to the end of the instant term. However, no options may be exercised.

(4) Continued eligibility of the participant with new ownership requires that CVE verify that all eligibility requirements are met by the concern and the new owners. Therefore, submissions made in accordance with paragraph (f)(1) of this section shall be treated as a reapplication and will be processed by CVE pursuant to section 74.14 of this part.

■ 5. Revise § 74.4 to read as follows:

§ 74.4 Who does CVE consider to control a veteran-owned small business?

(a) Control means the strategic policy, long-term decision-making authority, and the management of daily business operations for the VOSB. An applicant's or participant's management must be conducted by one or more veterans. Many persons share control of a concern, including each of those occupying the following positions: Officer, director, general partner, managing partner, managing member and manager. In addition, key employees who possess expertise or responsibilities related to the concern's primary economic activity may share significant control of the concern. CVE will consider the control potential of such key employees on a case-by-case basis.

(b) Control is not the same as ownership, although both may reside in the same person. CVE regards control as including both the strategic policy setting exercised by boards of directors and the management of daily business operations. Individuals managing the concern must have managerial experience of the extent and complexity needed to run the concern. A veteran need not have the technical expertise or possess a required license to be found to control an applicant or participant if he or she can demonstrate that he or she has ultimate managerial and supervisory control over those who possess the required license(s) or technical expertise. However, where a critical license(s) is held by a non-veteran having an equity interest in the applicant or participant firm, the non-veteran may be found to control the firm pursuant to paragraph (j)(2) of this section.

(c)(1) An applicant or participant must be controlled by one or more veterans who possess requisite management capabilities. Veteran owners need not work full-time but must show sustained and significant time invested in the business. A veteran owner engaged in employment or management outside the applicant concern must submit a written statement supplemental to the application which demonstrates that such activities will not have a significant impact on the owner's ability to manage and control the applicant concern. Applications from concerns

seeking joint-venture status are exempt from the requirement to submit a supplemental written statement.

(2) One or more veterans who manage the applicant or participant must devote full-time to the business during the normal working hours of firms in the same or similar line of business. Work in a wholly-owned subsidiary of the applicant or participant may be considered to meet the requirement of full-time devotion. This applies only to a subsidiary owned by the VOSB itself, and not to firms in which the veteran has a mere ownership interest.

(3) An eligible full-time manager must hold the highest officer position (usually President or Chief Executive Officer) in the applicant or participant.

(d) Except as provided in paragraph (h) of this section, a veteran owner's unexercised right to cause a change in the management of the applicant concern does not in itself constitute veteran control, regardless of how quickly or easily the right could be exercised.

(e) The veteran(s) upon whom eligibility is based must control the applicant or participant's governing body. Control may be established through actual numbers, voting based on ownership interest held by directors, members, managers or partners, bloc voting (*e.g.,* where two or more directors vote as a single block pursuant to a written agreement), or weighted voting (*e.g.,* in a concern having a two-person board of directors where one individual on the board is a veteran and one is not, the veteran vote must be weighted—worth more than one vote—in order for the concern to be eligible for VetBiz VIP Verification). Where a concern seeks to comply with this paragraph:

(1) The veteran(s) upon whom eligibility is based must have control over all decisions of the governing body, with the exception of extraordinary business decisions. Extraordinary business decisions include, but are not limited to, acceptance of new capital contributions, addition of members to an LLC or partnership, amendment of an operating or partnership agreement in a manner that materially alters members' rights, material amendments to bylaws, issuance of additional shares of capital stock, and the sale or lease of all or substantially all of a concern's assets.

(2) Provisions for the establishment of a quorum cannot permit non-veterans, such as directors, members, managers or partners to control the governing body, directly or indirectly;

(3) A veteran upon whom eligibility is based must be able to unilaterally amend the governing documents without requiring the consent of non-veterans, such as shareholders, directors, members, managers or partners, except amendments that are extraordinary business decisions;

(4) Any executive committee of the applicant's or participant's governing body must be controlled by veteran(s) acting as director(s) unless the executive committee can only make recommendations to and cannot independently exercise the authority of the board of directors;

(5) Non-voting, advisory, or honorary directors, members, managers or partners may be appointed without affecting veterans' control of the governing body.

(6) Arrangements regarding the structure and voting rights of the board of directors, or other governing bodies, must comply with applicable state law.

(f) In the case of a partnership, one or more veterans must serve as general partners, with control over all partnership decisions, except as provided in paragraph (e)(1). A partnership in which no veteran is a general partner will be ineligible for participation.

(g) In the case of a limited liability company, one or more veterans must serve as management members, with control over all decisions of the limited liability company, except as provided in paragraph (e)(1).

(h) In the case of a corporation, one or more veterans must control the board of directors of a corporate applicant or participant. CVE will deem veterans to control the board of directors when veterans owning at least 51% of voting stock have the power to unilaterally, or through a block voting agreement, remove any director at any time for any reason.

(i) Non-veterans may be involved in the management of an applicant or participant, and may be stockholders, partners, limited liability members, officers, or directors of the applicant or participant. However, with the exception of a surviving spouse, or permanent caregiver who represents a severely disabled veteran owner, no non-veteran or immediate family member may:

(1) Exercise actual control or have the power to control the applicant or participant;

(2) Be a former employer or a principal of a former employer of any affiliated business of the applicant or participant, unless it is determined by the CVE that the relationship between the former employer or principal and the eligible individual or applicant concern does not give the former employer actual control or the potential to control the applicant or participant and such relationship is in the best interests of the participant firm; or

(3) Receive compensation in any form, including distributions, from the applicant or participant as directors, officers or employees, which exceeds the compensation to be received by the highest officer (usually President or Chief Executive Officer). The highest ranking officer may elect to receive less compensation than a non-veteran only upon demonstrating that it helps the applicant or participant.

(j) Non-veterans or entities may be found to control or have the power to control in any of the following circumstances, which are illustrative only and not all inclusive:

(1) Non-veterans control the board of directors of the applicant or participant, either directly through majority voting membership, or indirectly, where the by-laws allow non-veterans effectively to prevent a quorum or block actions proposed by the veterans.

(2) A non-veteran or entity, having an equity interest in the applicant or participant, provides critical financial or bonding support or a critical license to the applicant or participant. For the purposes of this part, financing, bonding or licensure will be deemed critical where the withholding or withdrawal of the support may cause a business to fail to meet its financial obligations, may allow a non-veteran or entity to significantly influence business decisions, or may result in a dependent relationship with a non-veteran or entity.

(3) A non-veteran or entity controls the applicant or participant or an individual veteran owner through loan arrangements. Providing a loan guaranty on commercially reasonable terms does not, by itself, give a non-veteran or entity the power to control a firm.

(4) Business relationships exist with non-veterans or entities which cause such dependence that the applicant or participant cannot exercise independent business judgment without great economic risk.

■ 6. Revise § 74.5 to read as follows:

§ 74.5 How does CVE determine affiliation?

(a) CVE does not determine affiliation. Affiliation is determined by the SBA in accordance with 13 CFR part 121.

(b) Joint ventures may apply for inclusion in the VetBiz VIP Verification Program. To be eligible for inclusion in the VetBiz VIP Verification Program a joint venture must demonstrate that:

(1) The underlying VOSB upon which eligibility is based is verified in accordance with this part;

(2) The underlying VOSB upon which eligibility is based is entitled to at least 51% of the net profits earned by the joint venture;

(3) The joint venture agreement complies with the requirements set forth in 13 CFR 125.15(b)(2).

■ 7. Revise § 74.10 to read as follows:

§ 74.10 Where must an application be filed?

An application for VetBiz VIP Verification status must be electronically filed in the Vendor Information Pages database located on the CVE's Web portal, *http://www.VetBiz.gov.* Guidelines and forms are located on the Web portal. Upon receipt of the applicant's electronic submission, an acknowledgment message will be dispatched to the concern containing estimated processing time and other information. Address information for the CVE is also located on the Web portal.

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0675.)

■ 8. Revise § 74.11 to read as follows:

§ 74.11 How does CVE process applications for VetBiz VIP Verification Program?

(a) The Director, CVE, is authorized to approve or deny applications for VetBiz VIP Verification. CVE will receive, review and examine all VetBiz VIP Verification applications. CVE will advise each applicant within 30 days, when practicable, after the receipt of an application whether the application is complete and suitable for a verification examination and, if not, what additional information or clarification is required to complete the application. CVE will process an application for VetBiz VIP Verification status within 60 days, when practicable, of receipt of a complete application package. Incomplete application packages will not be processed.

(b) CVE, in its sole discretion, may request clarification of information relating to eligibility at any time in the eligibility determination process. CVE will take into account any clarifications made by an applicant in response to a request for such by CVE.

(c) CVE, in its sole discretion, may request additional documentation at any time in the eligibility determination process. Failure to adequately respond to the documentation request shall constitute grounds for a denial.

(d) An applicant's eligibility will be based on the totality of circumstances existing on the date of application, except where clarification is made pursuant to paragraph (b) of this section, additional documentation is submitted pursuant to paragraph (c) of this section, as provided in paragraph (e) of this section or in the case of amended documentation submitted pursuant to section 74.13(a) of this part. The applicant bears the burden to establish its status as a VOSB.

(e)(1) Changed circumstances for an applicant occurring subsequent to its application and which adversely affect eligibility will be considered and may constitute grounds for denial of the application. The applicant must inform CVE of any changed circumstances that could adversely affect its eligibility for the program (*i.e.,* ownership or control changes) during its application review.

(2) *Bankruptcy.* Bankruptcy is a change in circumstance requiring additional protection for the agency. Should a VOSB enter into bankruptcy the participant must:

(i). Inform CVE of the filing event within 30 days;

(ii). Specify to CVE whether the concern has filed Chapter 7, 11 or 13 under U.S. Bankruptcy code; and

(iii) Any participant that is performing contracts must assure performance to the contracting officer(s) prior to any reorganization or change if necessary including such contract's in the debtor's estate and reorganization plan in the bankruptcy.

(f) The decision of the Director, CVE, to approve or deny an application will be in writing. A decision to deny verification status will state the specific reasons for denial, and will inform the applicant of any appeal rights.

(g) If the Director, CVE, approves the application, the date of the Notice of Verified Status Approval letter is the date of participant verification for purposes of determining the participant's verification eligibility term.

(h) The decision may be sent by mail, commercial carrier, facsimile transmission, or other electronic means. It is the responsibility of the applicant to ensure all contact information is current in the applicant's profile.

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0675.)

■ 9. Revise § 74.12 to read as follows:

§ 74.12 What must a concern submit to apply for VetBiz VIP Verification Program?

Each VetBiz VIP Verification applicant must submit the VA Form 0877 and supplemental documentation as CVE requires. All electronic forms are available on the VetBiz.gov VIP database Web pages. From the time the applicant dispatches the VA Form 0877, the applicant must also retain on file, at the principal place of business, a complete copy of all supplemental documentation required by, and provided to, CVE for use in verification examinations. The documentation to be submitted to CVE includes, but is not limited to: Articles of Incorporation/Organization; corporate by-laws or operating agreements; shareholder agreements; voting records and voting agreements; trust agreements; franchise agreements, organizational, annual and board/member meeting records; stock ledgers and certificates; State-issued Certificates of Good Standing; contract, lease and loan agreements; payroll records; bank account signature cards; financial statements; Federal personal and business tax returns for up to 3 years; and licenses. These materials shall be filed together to maximize efficiency of verification examination visits, and will provide CVE with sufficient information to establish the management, control and operating status of the business on the date of submission.

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0675.)

■ 10. Revise § 74.13 to read as follows:

§ 74.13 Can an applicant ask CVE to reconsider its initial decision to deny an application?

(a) An applicant may request that the Director, CVE, reconsider his or her decision to deny an application by filing a request for reconsideration with CVE within 30 days of CVE sending the denial decision. ''Filing'' means a document is received by CVE by 11:59 p.m., Eastern Time, on that day. Requests for reconsideration must be submitted in accordance with the directions and to the address identified in the denial letter. The filing party bears the risk that the delivery method chosen will not result in timely receipt at CVE. An applicant may submit additional or amended documentation as directed by CVE.

(b) The Director, CVE, will issue a written decision within 60 days, when practicable, of receipt of the applicant's request. The Director, CVE, may either approve the application, deny it on the same grounds as the original decision, or deny it on other grounds. If denied, the Director, CVE, will explain why the applicant is not eligible for the VetBiz VIP Verification and give specific reasons for the denial.

(c) If the Director, CVE, denies the application solely on issues not raised in the initial denial, the applicant may

ask for reconsideration as if it were an initial denial.

(d) If CVE determines that a concern may not qualify as small, they may directly deny an application for VetBiz VIP Verification and may request a formal size determination from the SBA. A concern whose application is denied because it is other than a small business concern by CVE may request that CVE reconsider the decision pursuant to this section. A favorable determination by SBA will enable the firm to immediately submit a new VetBiz VIP Verification.

(e) A denial decision that is based on the failure to meet any veteran eligibility criteria is not subject to a request for reconsideration and is the final decision of CVE.

(f) Except as provided in paragraph (c) of this section, the decision on the request for reconsideration shall be final.

(g) The decision on the request for reconsideration may be sent by mail, commercial carrier, facsimile transmission, or other electronic means. It is the responsibility of the applicant to ensure all contact information is current in the applicant's profile.

■ 11. Revise § 74.14 to read as follows:

§ 74.14 Can an applicant or participant reapply for admission to the VetBiz VIP Verification Program?

(a) Once an application, a request for reconsideration, or an appeal of a verified status cancellation has been denied, or a verified status cancellation has been issued, the applicant or participant shall be required to wait for a period of 12 months before a new application will be processed by CVE.

(b) Participants may reapply prior to the termination of their eligibility period. If a participant is found to be ineligible the participant will forfeit any time remaining on their eligibility period and will be immediately removed from the VetBiz VIP Verification database. An applicant removed pursuant to this section may ask CVE to reconsider its decision in accordance with section 74.13 of this Part. The date of a new determination letter verifying an applicant will be the beginning of the next two-year eligibility period.

■ 12. Revise § 74.15 to read as follows:

§ 74.15 What length of time may a business participate in VetBiz VIP Verification Program?

(a) A participant receives an eligibility term of 2 years from the date of CVE's Notice of Verified Status Approval letter establishing verified status.

(b) The participant must maintain its eligibility during its tenure and must inform CVE of any changes that would adversely affect its eligibility within 30 days.

(c) The eligibility term may be shortened by removal pursuant to § 74.2 of this Part, application pursuant to § 74.14(b) of this Part, voluntary withdrawal by the participant pursuant to § 74.21 of this Part, or cancellation pursuant to § 74.22 of this Part.

(d) CVE may initiate a verification examination whenever it receives credible information concerning a participant's eligibility as a VOSB. Upon its completion of the examination, CVE will issue a written decision regarding the continued eligibility status of the questioned participant.

(e) If CVE finds that the participant does not qualify as a VOSB, the procedures at § 74.22 of this Part will apply, except as provided in § 74.2 of this Part.

(f) If CVE finds that the participant continues to qualify as a VOSB, the original eligibility period remains in effect.

■ 13. Revise § 74.20 to read as follows:

§ 74.20 What is a verification examination and what will CVE examine?

(a) *General.* A verification examination is an investigation by CVE officials, which verifies the accuracy of any statement or information provided as part of the VetBiz VIP Verification application process. Thus, examiners may verify that the concern currently meets the eligibility requirements, and that it met such requirements at the time of its application or its most recent size recertification. An examination may be conducted on a random, unannounced basis, or upon receipt of specific and credible information alleging that a participant no longer meets eligibility requirements.

(b) *Scope of examination.* CVE may conduct the examination at one or all of the participant's offices or work sites. CVE will determine the location(s) of the examination. CVE may review any information related to the concern's eligibility requirements including, but not limited to, documentation related to the legal structure, ownership and control. As a minimum examiners shall review any or all of the organizing documents, financial documents and publicly available information as well as any information identified in section 74.12 of this part.

■ 14. Revise § 74.21 to read as follows:

§ 74.21 What are the ways a business may exit VetBiz VIP Verification Program status?

A participant may:

(a) Voluntarily cancel its status by submitting a written request to CVE requesting that the concern be removed from public listing in the VIP database; or

(b) Delete its record entirely from the VIP database; or

(c) CVE may remove a participant immediately pursuant to § 74.2; or

(d) CVE may remove a participant from public listing in the VIP database for good cause upon formal notice to the participant. Examples of good cause include, but are not limited to, the following:

(1) Submission of false information in the participant's VetBiz VIP Verification application.

(2) Failure by the participant to maintain its eligibility for program participation.

(3) Failure by the participant for any reason, including the death of an individual upon whom eligibility was based, to maintain ownership, management, and control by veterans, service-disabled veterans or surviving spouses.

(4) Failure by the concern to disclose to CVE the extent to which non-veteran persons or firms participate in the management of the participant.

(5) A pattern of failure to make required submissions or responses to CVE or its agents, including a failure to make available financial statements, requested tax returns, reports, information requested by CVE or VA's Office of Inspector General, or other requested information or data within 30 days of the date of request.

(6) Cessation of the participant's business operations.

(7) Failure by the concern to provide an updated VA Form 0877 within 30 days of any change in ownership, except as provided in paragraph 74.3(f)(3) of this part.

(d) The examples of good cause listed in paragraph (c) of this section are intended to be illustrative only. Other grounds for canceling a participant's verified status include any other cause of so serious or compelling a nature that it affects the present responsibility of the participant.

(e) Failure to inform CVE of any such changed circumstances, as outlined in paragraphs (c) and (d) of this section, within 30 days constitutes cause for which CVE may cancel verified status of the participant.

■ 15. Amend § 74.22 by revising paragraphs (a) and (e) to read as follows:

§ 74.22 What are the procedures for cancellation?

(a) *General.* When CVE believes that a participant's verified status should be cancelled prior to the expiration of its eligibility term, CVE will notify the

participant in writing. The Notice of Proposed Cancellation Letter will set forth the specific facts and reasons for CVE's findings, and will notify the participant that it has 30 days from the date CVE sent the notice to submit a written response to CVE explaining why the proposed ground(s) should not justify cancellation.

* * * * *

(e) *Appeals.* A participant may file an appeal with the Executive Director, OSDBU, concerning the Notice of Verified Status Cancellation within 30 days of receipt of CVE's cancellation decision. ''Filing'' means a document is received by CVE by 5:30 p.m., eastern time, on that day. Documents may be filed by hand delivery, mail, commercial carrier, or facsimile transmission. Hand delivery and other means of delivery may not be practicable during certain periods due, for example, to security concerns or equipment failures. The filing party bears the risk that the delivery method chosen will not result in timely receipt at CVE. Submit appeals to: Executive Director, Office of Small and Disadvantaged Business Utilization and Center for Veterans Enterprise (00VE), U.S. Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420. A formal decision will be issued within 60 days after receipt. The decision on the appeal shall be final.

■ 16. Revise § 74.25 to read as follows:

§ 74.25 What types of personally identifiable information will VA collect?

In order to establish owner eligibility, VA will collect individual names and Social Security numbers of all owners who represent themselves as having ownership interests in a specific business seeking to obtain verified status.

■ 17. Revise § 74.26 to read as follows:

§ 74.26 What types of business information will VA collect?

VA will examine a variety of business records. See section 74.12, ''What must a concern submit to apply for VetBiz VIP Verification Program?''

■ 18. Revise § 74.27 to read as follows:

§ 74.27 How will VA store information?

VA stores records provided to CVE fully electronically on the VA's secure servers. CVE personnel will compare information provided concerning owners against any available records. Any records collected in association with the VetBiz VIP verification program will be stored and fully secured in accordance with all VA records management procedures. Any data breaches will be addressed in accordance with the VA information security program.

■ 19. Revise § 74.28 to read as follows:

§ 74.28 Who may examine records?

Personnel from VA, CVE and its agents, including personnel from the SBA, may examine records to ascertain the ownership and control of the applicant or participant.

■ 20. Revise § 74.29 to read as follows:

§ 74.29 When will VA dispose of records?

The records, including those pertaining to businesses not determined to be eligible for the program, will be kept intact and in good condition and retained in accordance with VA records management procedures following a program examination or the date of the last Notice of Verified Status Approval letter. Longer retention will not be required unless a written request is received from the Government Accountability Office not later than 30 days prior to the end of the retention period.

(Authority: 38 U.S.C. 8127(f))

[FR Doc. 2015–28256 Filed 11–5–15; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0643; FRL–9935–64–Region 9]

Revisions to the California State Implementation Plan, Placer County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Placer County portion of the California State Implementation Plan (SIP). This revision concerns the necessary procedures to create emission reduction credits (ERCs) from the reduction of volatile organic compound (VOC), oxides of nitrogen (NO_X), oxides of sulfur (SO_X), particulate matter (PM), and carbon monoxide (CO) emissions due to the use and installation of a control device on stationary locomotive engines in rail yards. We are proposing to approve a local rule that provides administrative procedures for creating emissions reduction credits, consistent with Clean Air Act (CAA or the Act) requirements.

DATES: Any comments on this proposal must arrive by December 7, 2015.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2015–0643, by one of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.

2. *Email: steckel.andrew@epa.gov.*

3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you need to include CBI as part of your comment, please visit *http://www.epa.gov/dockets/comments.html* for further instructions. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. For the full EPA public comment policy and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/comments.html.*

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Nancy Levin, EPA Region IX, (415) 972–3848, *levin.nancy@epa.gov.*

SUPPLEMENTARY INFORMATION: This proposal addresses the following local rule: Placer County Air Pollution Control District Rule 515 Stationary Rail Yard Control Emission Reduction Credits. In the Rules and Regulations section of this **Federal Register**, we are approving this local rule in a direct final action without prior proposal because we believe this SIP revision is not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in

subsequent action based on this proposed rule.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: September 25, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2015–28271 Filed 11–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2014–0866; FRL–9935–90–OAR]

RIN 2060–AS43

Standards of Performance for Stationary Compression Ignition Internal Combustion Engines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing amendments to the standards of performance for stationary compression ignition (CI) internal combustion engines to allow manufacturers to design the engines so that operators can temporarily override performance inducements related to the emission control system for stationary CI internal combustion engines operating during emergency situations where the operation of the engine or equipment is needed to protect human life, and to require compliance with Tier 1 emission standards during such emergencies. The EPA is also proposing to amend the standards of performance for certain stationary CI internal combustion engines located in remote areas of Alaska.

DATES: Comments must be received on or before December 21, 2015.

Public hearing. If anyone contacts us requesting to speak at a public hearing by November 13, 2015, a public hearing will be held on November 23, 2015. If you are interested in attending the public hearing, contact Ms. Melanie King at (919) 541–2469 or *king.melanie@epa.gov* to verify that a hearing will be held.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2014–0866, to the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

The EPA requests that you also submit a separate copy of your comments to the contact person identified below (see **FOR FURTHER INFORMATION CONTACT**). If the comment includes information you consider to be CBI or otherwise protected, you should send a copy of the comment that does not contain the information claimed as CBI or otherwise protected.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. The EPA also relies on materials in Docket ID Nos. EPA–HQ–OAR–2008–0708, EPA–HQ–OAR–2010–0295, and EPA–HQ–OAR–2011–1032, and incorporates those dockets into the record for this proposed rule.

Although listed in the index, some information is not publicly available (*e.g.,* CBI or other information whose disclosure is restricted by statute). Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742. Visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm* for additional information about the EPA's public docket.

In addition to being available in the docket, an electronic copy of this proposed rule will be available on the World Wide Web (WWW). Following signature, a copy of this proposed rule will be posted at the following address: *http://www.epa.gov/ttn/atw/icengines/.*

Public hearing: If anyone contacts the EPA requesting a public hearing by November 13, 2015, the public hearing will be held on November 23, 2015 at the EPA's campus at 109 T.W. Alexander Drive, Research Triangle Park, North Carolina. Please contact Ms. Melanie King at (919) 541–2469 or at *king.melanie@epa.gov* to register to speak at the hearing or to inquire as to whether or not a hearing will be held.

FOR FURTHER INFORMATION CONTACT: Ms. Melanie King, Energy Strategies Group, Sector Policies and Programs Division (D243–01), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2469; facsimile number: (919) 541–5450; email address: *king.melanie@epa.gov.*

SUPPLEMENTARY INFORMATION:

Organization of this document. The information presented in this preamble is organized as follows:

I. General Background

On July 11, 2006, the EPA promulgated standards of performance

for stationary CI internal combustion engines (71 FR 39154). These standards, known as new source performance standards (NSPS), implement section 111(b) of the Clean Air Act (CAA), and are issued for categories of sources that cause, or contribute significantly to, air pollution that may reasonably be anticipated to endanger public health or welfare. The standards apply to new stationary sources of emissions, *i.e.,* sources whose construction, reconstruction, or modification begins after a standard for those sources is proposed. The NSPS for stationary CI internal combustion engines established limits on emissions of particulate matter (PM), nitrogen oxides (NO_X), carbon monoxide (CO) and non-methane hydrocarbons (NMHC). The emission standards are generally modeled after the EPA's standards for nonroad and marine diesel engines. The nonroad CI engine standards are phased in over several years and have Tiers with increasing levels of stringency. The engine model year in which the Tiers take effect varies for different size ranges of engines. The Tier 4 final standards for new stationary non-emergency and nonroad CI engines generally begin with either the 2014 or 2015 model year.

In 2011, the EPA finalized revisions to the NSPS for stationary CI engines that amended the standards for engines with a displacement greater than 10 liters per cylinder, and also for engines located in remote areas of Alaska (76 FR 37954). In this action, the EPA is proposing amendments to the NSPS regarding performance inducements for Tier 4 engines and the criteria for defining remote areas of Alaska. The proposed amendments are discussed below.

II. Temporary Override of Inducements in Emergency Situations

A. Background

Many Tier 4 final engines are equipped by the engine manufacturer with selective catalytic reduction (SCR) to reduce emissions of NO_X. The consumable reactant in an SCR system is typically supplied as a solution of urea in water known as diesel exhaust fluid (DEF). Engines equipped with SCR generally include controls that limit the function of the engines if they are operated without DEF, or if the engine's electronic control module cannot otherwise confirm that the SCR system is properly operating. Such controls are generally called ''inducements'' because they induce the operator to properly maintain the SCR emission control system. In normal circumstances, if inducements begin, the engine operator is expected to perform any necessary maintenance to avoid shutdown. Manufacturers as well as owners and operators of nonroad and stationary CI Tier 4 certified engines have raised concerns regarding the inducements being triggered and engines shutting down during emergency situations. Triggers could include a temporary supply shortage of DEF, a freeze warning, a blocked DEF hose, or a disconnected or faulty DEF pump or sensor. These inducements can be triggered because of an actual emission problem (such as a blocked DEF line or an empty DEF tank), or because of a sensor problem that reports a false positive problem even though the emission controls are still functioning properly. While the EPA is confident that DEF is now widely available and easily obtainable across the United States, the EPA is concerned that in emergency circumstances, such as the aftermath of storms like Hurricane Sandy or Hurricane Katrina, there may be a possibility of temporary disruptions in DEF supply, disruptions in communications between operators and service centers, or delays in response time for engine repair service. In an emergency situation, allowing inducements to impact engine performance may endanger human lives for engines that are providing life-saving emergency service, such as engines providing emergency power for a hospital. As an example, the Johns Hopkins Health System indicated that the availability of emergency power ''can be the difference between life and death for critically ill patients. Disruption of emergency power for any reason could have catastrophic results for patients in surgery, for patients on respirators, and for patients receiving medical gases, to name a few.'' (See Docket ID No. EPA–HQ–OAR–2014–0866.)

The EPA's existing nonroad and stationary engine compliance regulations in 40 CFR 1068.101(b)(1)(ii) allow operators to temporarily disable or remove emission controls to address emergency situations, with a limited exemption from the prohibition that normally applies for tampering with certified engines.[1] However, until recently, the regulations did not allow manufacturers to design the emission controls to be disabled or removed in emergency situations. With modern electronically controlled engines, many emission controls are integrated into the engine's control software, and there is no way for the operator to selectively disable emission control software, while maintaining engine function. In order to permit engine manufacturers to design the emission controls to be disabled or removed in emergency situations, the EPA amended the emission standards for nonroad CI engines to allow manufacturers of nonroad CI engines to give operators the means to temporarily override inducements while operating in emergency situations (79 FR 46356, August 8, 2014). At that time, the EPA indicated that the amendments did not apply to stationary CI engines. Engine manufacturers and owners and operators of stationary CI engines have indicated that it would be appropriate to extend the provisions to stationary CI engines, since they can also be used in emergency situations, and many engines are dual-certified for both nonroad and stationary use. To address concerns about stationary CI engines shutting down during emergency situations and endangering human lives, the EPA is proposing in this action to allow manufacturers of stationary CI engines certified to the Tier 4 standards to give operators the means to temporarily override inducements while operating in qualified emergency situations. The EPA is also proposing to require engine operators to meet the Tier 1 emission standard in 40 CFR 89.112 that applies to the engine's rated power during the qualified emergency situation. The specific amendments the EPA is proposing are discussed in more detail below. If adopted, these provisions will make available stationary engines that will allow operators to use the flexibility already provided under 40 CFR 1068.101(b)(1)(ii) to ensure that emission controls will not impede the engine from providing life-saving emergency service. The flexibility the EPA is adopting is very narrow and contains several provisions to ensure the need for the relief.

B. Proposed Amendments

As discussed previously, on August 8, 2014, the EPA promulgated provisions allowing manufacturers of nonroad engines certified to the emission standards in 40 CFR part 1039 to give operators the means to temporarily override emission control inducements while operating in emergency situations, such as those where operation of the engine is needed to protect human life (79 FR 46356). These provisions, which are codified in 40 CFR 1039.665, allow for auxiliary emission control devices (AECDs) that help to ensure proper function of

[1] ''This [tampering] prohibition does not apply in any of the following situations: . . . (ii) You need to modify the engine/equipment to respond to a temporary emergency and you restore it to proper functioning as soon as possible.'' 40 CFR 1068.101(b)(1)(ii).

engines in emergency situations. AECDs are any element of design that senses temperature, motive speed, engine revolutions per minute, transmission gear, or any other parameter for the purpose of activating, modulating, delaying, or deactivating the operation of any part of the emission control system. The provisions of 40 CFR 1039.665 allow the engine manufacturer to include a dormant feature in the engine's control software that could be activated to override emission control inducements. In this action, the EPA is proposing to adopt those same provisions for stationary CI engines certified to the standards in 40 CFR part 1039 and used in qualified emergency situations. It is important to emphasize that the EPA is confident that Tier 4 engines will function properly in the vast majority of emergency situations. Thus, the EPA expects that AECDs allowed under this proposed provision will rarely be activated. The EPA is proposing this provision merely as a precaution to ensure that stationary CI engines can continue to operate in emergencies.

The proposed amendments allow engine manufacturers to design into their stationary CI engines a dormant AECD that can be activated for up to 120 engine hours per use during a qualified emergency situation to prevent emission controls from interfering with engine operation. The EPA is proposing that engine manufacturers can offer, and operators can request, re-activations of the AECD for additional time in increments of 120 engine hours in cases of a prolonged emergency situation. During the emergency situation, the engine must meet the Tier 1 emission standard in 40 CFR 89.112 that applies to the engine's rated power. Operators activating the AECD will be required to report the incident to the engine manufacturers, and engine manufacturers will submit an annual report to the EPA summarizing the use of these AECDs during the prior year. These proposed amendments are discussed in more detail below.

1. Definition of Qualified Emergency Situation

The EPA is proposing to use the definition of qualified emergency situation established in the August 8, 2014, amendments for nonroad engines. This definition is found in the introductory text to 40 CFR 1039.665, and specifies that a qualified emergency situation is one in which the condition of an engine's emission controls poses a significant direct or indirect risk to human life. An example of a direct risk would be an emission control condition that inhibits the performance of an engine being used to rescue a person from a life-threatening situation (for example, providing power to a medical facility during an emergency situation). An example of an indirect risk would be an emission control condition that inhibits the performance of an engine being used to provide electrical power to a data center that routes ''911'' emergency response telecommunications.

2. Basic AECD Criteria

Section 1039.665 specifies provisions allowing for AECDs that are necessary to ensure proper function of engines and equipment in emergency situations. It also includes specific criteria that the engine manufacturer must meet to ensure that any adverse environmental impacts are minimized. These criteria are:

- The AECD must be designed so that it cannot be activated more than once without the specific permission of the certificate holder. Reactivation of the AECD must require the input of a temporary code or equivalent security feature.
- The AECD must become inactive within 120 engine hours of becoming active. The engine must also include a feature that allows the operator to deactivate the AECD once the emergency is over.
- The manufacturer must show that the AECD deactivates emission controls (such as inducement strategies) only to the extent necessary to address the expected emergency situation.
- The engine controls must be configured to record in non-volatile electronic memory the total number of activations of the AECD for each engine.
- The manufacturer must take appropriate additional steps to induce operators to report AECD activation and request resetting of the AECD. The EPA recommends including one or more persistent visible and/or audible alarms that are active from the point when the AECD is activated to the point when it is reset.
- The manufacturer must provide purchasers with instructions on how to activate the AECD in emergency situations, as well as information about penalties for abuse.

3. Emission Standards During Qualified Emergency Situations

The EPA is proposing to require stationary CI engines to meet different emission standards for the very narrow period of operation where there is an emergency situation with a risk to human life and the owner or operator is warned that the inducement is about to occur. The EPA is proposing that the emission standards that apply when the AECD is activated during the qualified emergency situation are the Tier 1 standards in 40 CFR 89.112. Engine manufacturers indicated that meeting the Tier 2 or 3 standards in 40 CFR 89.112 is not feasible because the base engine used in Tier 4 configurations does not have exhaust gas recirculation (EGR), which is the engine design technology used to meet the Tier 2 and 3 standards. The EGR is not needed for Tier 4 because NO_X is controlled by the SCR.[2] The Tier 1 requirement applies only when there is a qualified emergency situation and bypass of inducements is necessary to ensure continued operation of the engine. Once the emergency situation has ended and the AECD is deactivated, the engine must comply with the otherwise applicable emission standard specified in 40 CFR 60.4202. Engine manufacturers must provide data demonstrating that the engine complies with the Tier 1 standard when the AECD is activated when applying for certification of an engine equipped with an AECD.

4. Approval, Recordkeeping and Reporting for Engine Manufacturers

Manufacturers may ask for approval of the use of emergency AECDs at any time; however, the EPA encourages manufacturers to obtain preliminary approval before submitting an application for certification. Otherwise, the EPA's review of the AECD, which may include many unique features, may delay the approval of the application for certification.

The manufacturer is required to keep records to document the use of emergency AECDs until the end of the calendar year 5 years after the onset of the relevant emergency situation. The manufacturer must submit an annual compliance report to the EPA within 90 calendar days of the end of each calendar year in which it authorizes use of an AECD. The annual report must include a description of each AECD activation and copies of the reports submitted by owners or operators (or statements that an owner or operator did not submit a report, to the extent of the manufacturer's knowledge). If an owner or operator fails to report the use of an emergency AECD to the manufacturer, the manufacturer, to the extent it has been made aware of the AECD activation, must send written notification to the operator that failure to meet the submission requirements may subject the operator to penalties.

[2] See Docket Id No. EPA–HQ–OAR–2014–0866.

5. Engine Owner or Operator Requirements

Owners or operators who purchase engines with this dormant feature will receive instructions from the engine manufacturer on how to activate the AECD in qualified emergency situations, as well as information about penalties for abuse. The EPA would consider appropriate use of this feature to be during a situation where operation of a stationary CI engine is needed to protect human life (or where impaired operation poses a significant direct or indirect risk to human life), and temporarily overriding emission controls enables full operation of the equipment. The EPA is adopting this provision to give operators the means to obtain short-term relief one time without the need to contact the engine manufacturer or the EPA. In a qualified emergency situation, delaying the activation to obtain approval could put lives at risk, and would be unacceptable. However, the EPA retains the authority to evaluate, after the fact, whether it was reasonable to judge that there was a significant risk to human life to justify the activation of the AECD. Where the EPA determines that it was not reasonable to judge (1) that there was a significant risk to human life; or (2) that the emission control strategy was curtailing the ability of the engine to perform, the owner or operator may be subject to penalties for tampering with emission controls. The owner or operator requirements also include a specific prohibition on operating the engine with the AECD beyond the time reasonably needed for such operation. The owner or operator may also be subject to penalties for tampering if they continue to operate the engine with the AECD once the emergency situation has ended or the problem causing the emission control strategy to interfere with the performance of the engine has been or can reasonably be fixed. Nevertheless, the EPA will consider the totality of the circumstances when assessing penalties, and retain discretion to reduce penalties where the EPA determines that an owner or operator acted in good faith.

The owner or operator must send a written report to the engine manufacturer within 60 calendar days after activating an emergency AECD. If any consecutive reactivations occur, this report is still due 60 calendar days from the first activation. The report must include:

- Contact name, mail and email addresses, and telephone number for the responsible company or entity.
- A description of the emergency situation, the location of the engine during the emergency, and the contact information for an official who can verify the emergency situation (such as a county sheriff, fire marshal, or hospital administrator).
- The reason for AECD activation during the emergency situation, such as the lack of DEF, or the failure of an emission-related sensor when the engine was needed to respond to an emergency situation.
- The engine's serial number (or equivalent).
- A description of the extent and duration of the engine operation while the AECD was active, including a statement describing whether or not the AECD was manually deactivated after the emergency situation ended.

Paragraph 1039.665(g) specifies that failure to provide this information to the engine manufacturer within the deadline is improper use of the AECD and is prohibited.

III. Remote Areas of Alaska

A. Background

1. Original Request From the State of Alaska

The 2006 final NSPS for CI internal combustion engines included a provision that allowed the state of Alaska to submit for EPA approval through rulemaking process an alternative plan for implementing the requirements of the NSPS for public-sector electric utilities located in rural areas of Alaska not accessible by the Federal Aid Highway System (FAHS). The alternative plan was required to be based on the requirements of section 111 of the CAA, including any increased risks to human health and the environment, and was also required to be based on the unique circumstances related to remote power generation, climatic conditions, and serious economic impacts resulting from implementation of the final NSPS.

The EPA communicated with officials from the state of Alaska on several occasions following the promulgation of the 2006 final rule. On October 31, 2008, the EPA received Alaska's request for several revisions to the NSPS as it pertained to engines located in the remote part of Alaska not served by the FAHS.[3] After reviewing the information provided by the state of Alaska, the EPA agreed that the circumstances in remote Alaska required special rules. On June 28, 2011, the EPA promulgated several amendments for engines used in remote Alaska (76 FR 37954). The amendments of relevance for this action are as follows:

- Exempting all pre-2014 model year engines from diesel fuel sulfur requirements;
- Allowing owners and operators of stationary CI engines located in remote areas of Alaska to use engines certified to marine engine standards, rather than land-based nonroad engine standards;
- Removing requirements to meet emission standards that would necessitate the use of aftertreatment devices for NO_X, in particular, SCR, for engines used in remote Alaska (emission standards that are not based on the use of aftertreatment devices for NO_X do apply);
- Removing requirements to meet emission standards that would necessitate the use of aftertreatment devices for PM until the 2014 model year; and
- Allowing the blending of used lubricating oil, in volumes of up to 1.75 percent of the total fuel, if the sulfur content of the used lubricating oil is less than 200 parts per million (ppm) and the used lubricating oil is ''on-spec,'' *i.e.,* it meets the on-specification levels and properties of 40 CFR 279.11.

In support of its October 31, 2008, request, the state of Alaska noted that remote communities in Alaska that are not accessible by the FAHS rely on diesel engines and fuel for electricity. These communities are scattered over long distances in remote areas and are not connected to population centers by road or power grid. These communities are located in the most severe arctic environments in the United States.

The state of Alaska noted that remote villages in Alaska use combined heat and power cogeneration plants, which are vital to their economy, given the high cost of fuel and the substantial need for heat in that climate. Heat recovery systems are used with diesel engines in remote communities to provide heat to community facilities and schools. Marine-jacketed diesel engines are used wherever possible because of their superior heat recovery and thermal efficiency. The state of Alaska indicated that they have noticed great reductions in heat recovery when using Tier 3 non-marine engines. The state noted that reductions in fuel efficiency will lead to greater fuel use and greater emissions from burning extra heating oil. The EPA agreed with the state that there are significant benefits from using marine engines, and finalized a revision allowing engines in remote Alaska to use marine-certified engines. However, as the state of Alaska noted, marine-certified engines,

[3] Docket item No. EPA–HQ–OAR–2010–0295–0012.

particularly those below 800 horsepower (HP), are not required to meet more stringent requirements for reduction of PM emissions, which is the most significant pollutant of concern in these areas. Therefore, the EPA required that owners and operators of 2014 model year and later engines in remote areas of Alaska must either be certified to Tier 4 standards (whether land-based nonroad or marine) or must install PM reduction technologies on their engines to achieve at least 85 percent reduction in PM.

The original request from the state of Alaska noted particular concern with NO_X standards that would likely entail the use of SCR in remote Alaska. NO_X reductions are particularly important in areas where ozone is a concern, because NO_X is a precursor to ozone. However, the state of Alaska, and remote Alaska in particular, does not have any significant ozone problems. Moreover, the use of SCR entails the supply, storage, and use of a DEF that needs to be used properly in order to achieve the expected emissions reductions, and that may have additional operational problems in remote arctic climates. As noted above, these villages are scattered over long distances in remote areas and are not connected to population centers by road or power grid. The villages are located in the most severe arctic environments in the United States and they rely on stationary diesel engines and fuel for electricity and heating, and these engines need to be in working condition, particularly in the winter. The availability of DEF in remote villages may be an issue, which is notable given the importance of the stationary engines in these villages. Furthermore, the costs for the acquisition, storage, and handling of the DEF are greater than for engines located elsewhere in the United States due to the remote location and severe arctic climate of the villages. In order to maintain proper availability of the DEF during the harsh winter months, new heated storage vessels may be needed at each engine facility, further increasing the compliance costs for these remote villages. Given the issues that would need to be addressed if SCR were required, and the associated costs of this technology when analyzed under NSPS guidelines, the EPA agreed with the state of Alaska's argument that it is inappropriate to require such standards for stationary engines in remote Alaska[4] and amended the NSPS for stationary CI internal combustion engines to specify that owners and operators of new stationary engines in remote areas of Alaska do not have to meet the Tier 4 standards for NO_X. However, owners and operators of model year 2014 and later engines that do not meet the Tier 4 p.m. standards would be required to use PM aftertreatment that achieves PM reductions of at least 85 percent. The use of PM aftertreatment will also achieve reductions in CO and NMHC.

Finally, regarding allowing owners and operators to blend up to 1.75 percent used oil into the fuel system, the state noted that there are no permitted used oil disposal facilities in remote Alaskan communities. The state has developed a cost-effective and reliable used-oil blending system that is currently being used in many remote Alaskan communities, disposing of the oil in an environmentally beneficial manner and capturing the energy content of the used oil. The absence of allowable blending would necessitate the shipping out of the used oil and would risk improper disposal and storage, as well as spills. According to the state, blending waste oil at 1.75 percent or less will keep the fuel within American Society for Testing and Materials (ASTM) specifications if the sulfur content of the waste oil is below 200 ppm. The state acknowledged the need for engines equipped with aftertreatment devices to use fuel meeting the sulfur requirements. The EPA agreed that the limited blending of used oil into the diesel fuel used by stationary engines in remote Alaska is an environmentally beneficial manner of disposing of such oil and is of little to no concern when kept within appropriate limits. Therefore, the EPA finalized amendments that permit the blending of fuel oil at such levels for engines in remote Alaska. The used oil must be ''on-spec,'' *i.e.,* it must meet the on-specification levels and properties in 40 CFR 279.11.

2. New Request From the State of Alaska

On November 28, 2014, the EPA received a new request from the state of Alaska, which can be found in the docket for this rulemaking. The request asked that the EPA revise the criteria for remote areas of Alaska, which were established in the 2011 amendments as areas that are not accessible by the FAHS, to also include areas that are accessible by the FAHS, but face similar challenges to areas that are not accessible. The letter recommended that the EPA adopt the same definition for remote areas of Alaska in the NSPS that was adopted in the 2013 amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Reciprocating Internal Combustion Engines (RICE), which can be found at 40 CFR part 63, subpart ZZZZ. The RICE NESHAP definition specifies that engines in areas that are accessible by the FAHS can be considered remote if each of the following conditions is met: (1) The only connection to the FAHS is through the Alaska Marine Highway System, or the stationary CI engine operation is within an isolated grid in Alaska that is not connected to the statewide electrical grid referred to as the Alaska Railbelt Grid; (2) at least 10 percent of the power generated by the engine on an annual basis is used for residential purposes; and (3) the generating capacity of the facility is less than 12 megawatts, or the engine is used exclusively for backup power for renewable energy.[5]

The state of Alaska provided information in a March 2, 2015, letter to the EPA to show that the communities in these additional FAHS-accessible areas face similar challenges to the communities in areas that are not accessible by the FAHS, and that the concerns that led to the 2011 amendments to the NSPS are also valid for the additional areas. As discussed previously, these challenges include inaccessibility, expense for DEF transport and storage, risk of engine shutdown, shortage of trained operators, and availability and cost of Tier 4 engines. The state noted that some of the communities are only accessible by road for a few months each year, or only by weekly ferry service; the alternative travel method is by floatplane. Thus, the delivery of DEF and the travel for engine service technicians to these areas would be much more costly than for areas that are not remote. The need to heat the DEF in the communities with a severe arctic climate would divert heat that is routinely used for space heating. Communities in these areas rely on diesel engines for electricity and heating, similar to the communities that are in areas that are not accessible by the FAHS, and failure of the engine to operate due to a shortage of DEF could present a risk to human life. The communities also have difficulty finding and retaining trained operators for the engines and aftertreatment devices, according to the state of Alaska.[6]

[4] Note that this action applies to stationary engines only; it is unlikely that such an approach would be appropriate for mobile engines, given that they are less permanent in a village and can move in and out of areas as work requires.

[5] See 40 CFR 63.6603(b).

[6] The state noted in its letter that nonroad engines are typically brought in temporarily by contractors and, therefore, the concerns raised for stationary engines are not necessarily applicable for nonroad engines.

Based on the information provided by the state, the EPA agrees that the circumstances that warranted different emission standards for new stationary CI internal combustion engines in areas of Alaska that are not accessible by the FAHS are also present in the additional FAHS-accessible remote areas identified in the RICE NESHAP definition.

B. Proposed Amendments

The EPA is proposing an amendment to the NSPS for stationary CI internal combustion engines that would align the definition of remote areas of Alaska with the definition currently used in the RICE NESHAP. The amendments specify that engines in areas that are accessible by the FAHS can be considered remote if each of the following conditions is met: (1) The only connection to the FAHS is through the Alaska Marine Highway System, or the stationary CI engine operation is within an isolated grid in Alaska that is not connected to the statewide electrical grid referred to as the Alaska Railbelt Grid; (2) at least 10 percent of the power generated by the engine on an annual basis is used for residential purposes; and (3) the generating capacity of the facility is less than 12 megawatts, or the engine is used exclusively for backup power for renewable energy. The Alaska Railbelt Grid is defined as the service areas of the six regulated public utilities that extend from Fairbanks to Anchorage and the Kenai Peninsula. These utilities are Golden Valley Electric Association; Chugach Electric Association; Matanuska Electric Association; Homer Electric Association; Anchorage Municipal Light & Power; and the City of Seward Electric System.

The following provisions that are currently present in the NSPS for stationary CI internal combustion engines for engines that are located in areas of Alaska that are not accessible by the FAHS will be extended to stationary CI internal combustion engines located in the areas identified above:

- Exemption for all pre-2014 model year engines from diesel fuel sulfur requirements;
- Allowance for owners and operators of stationary CI engines to use engines certified to marine engine standards, rather than land-based nonroad engine standards;
- No requirement to meet emission standards that would necessitate the use of aftertreatment devices for NO_X, in particular, SCR (emission standards that are not based on the use of aftertreatment devices for NO_X will apply);
- No requirement to meet emission standards that would necessitate the use of aftertreatment devices for PM until the 2014 model year; and
- Allowance for the blending of used lubricating oil, in volumes of up to 1.75 percent of the total fuel, if the sulfur content of the used lubricating oil is less than 200 ppm and the used lubricating oil is ''on-spec,'' *i.e.,* it meets the on-specification levels and properties of 40 CFR 279.11.

IV. Impacts of the Proposed Action

A. Economic Impacts

The EPA does not expect any significant economic impacts as a result of this proposed rule. A significant economic impact for the amendment allowing the temporary override of inducements in emergency situations is not anticipated because AECDs are expected to be activated rarely (if ever), and, thus, the impacts to affected sources and consumers of affected output will be minimal.

The economic impact from the change to the criteria for remote areas of Alaska will be a cost savings for owners or operators of engines that are located in the additional areas that will now be considered remote. The precise savings depends on the number and size of engines that will be installed each year. Information provided by the Alaska Energy Authority indicated that one to two new engines are expected to be installed each year. Information provided by the state of Alaska indicated that the expected initial capital cost savings per engine ranges from $28,000 to $163,000, depending on the size of the engine. There will also be annual operating and maintenance cost savings due to avoidance of the need to obtain and store DEF.

B. Environmental Impacts

The EPA does not expect any significant environmental impacts as a result of the proposed amendment to allow a temporary override of inducements in emergency situations. The AECDs are expected to be activated rarely (if ever) and will only affect emissions for a very short period.

The EPA also does not expect significant environmental impacts as a result of the proposed amendments to the criteria for remote areas of Alaska. As an example, allowing the use of a Tier 3 engine instead of a Tier 4 engine would result in less reductions for a 250 HP stationary CI engine of 5.4 tons per year (tpy) of NO_X, 0.1 tpy of NMHC, 1.6 tpy of CO, and 0.3 tpy of PM, assuming the engine operates full time (8,760 hours per year).[7] As stated previously, the state of Alaska estimates that only one to two new engines will be installed each year in the additional remote areas.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review, and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2060–0590. The proposed regulatory relief for stationary CI engines would be voluntary and optional.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. As mentioned earlier in this preamble, the EPA is harmonizing the NSPS for stationary CI engines in this action with an existing rule issued by the EPA for nonroad CI engines. Thus, this action is reducing regulatory impacts to small entities as well as other affected entities. The EPA is also including additional remote areas of Alaska in the regulatory flexibility provisions already in the rule for remote areas of Alaska, which further reduces the burden of the existing rule on small entities and other

[7] Estimates are based on Tier 3 and Tier 4 emission factors for a 175–300 HP engine provided in Table A4 of Exhaust and Crankcase Emission Factors for Nonroad Engine Modeling—Compression-Ignition. NR–009d. Assessment and Standards Division, Office of Transportation and Air Quality. U.S. Environmental Protection Agency. EPA–420–R–10–018. July 2010. *http://www.epa.gov/otaq/models/nonrdmdl/nonrdmdl2010/420r10018.pdf.*

affected entities. We have, therefore, concluded that this action will relieve regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector. This action does not contain a federal mandate that may result in expenditures of $100 million or more for the private sector in any one year. Engine manufacturers have the flexibility to choose whether or not to use optional AECDs.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175. This proposed rule would impose compliance costs primarily on engine manufacturers, depending on the extent to which they take advantage of the flexibilities offered. The proposed amendments to expand the areas that are considered remote areas of Alaska would reduce the compliance costs for owners and operators of stationary engines in those areas. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations. The provisions being proposed in this action are designed to eliminate risks to human life and are expected to be used rarely, if at all, and will only affect emissions for a very short period. Other changes the EPA is proposing to make have minimal effect on emissions.

List of Subjects in 40 CFR Part 60

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: October 30, 2015.

Gina McCarthy,

Administrator.

For the reasons stated in the preamble, title 40, chapter I, part 60 of the Code of the Federal Regulations is proposed to be amended as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart IIII—Standards of Performance for Stationary Compression Ignition Internal Combustion Engines

■ 2. Amend § 60.4201 by revising paragraph (f)(1) and adding paragraph (h) to read as follows:

§ 60.4201 What emission standards must I meet for non-emergency engines if I am a stationary CI internal combustion engine manufacturer?

* * * * *

(f) * * *

(1) Remote areas of Alaska; and

* * * * *

(h) Stationary CI ICE certified to the standards in 40 CFR part 1039 and equipped with auxiliary emission control devices (AECDs) as specified in 40 CFR 1039.665 must meet the Tier 1 certification emission standards for new nonroad CI engines in 40 CFR 89.112 while the AECD is activated during a qualified emergency situation. When the qualified emergency situation has ended and the AECD is deactivated, the engine must resume meeting the otherwise applicable emission standard specified in this section.

■ 3. Amend § 60.4202 by revising paragraph (g)(1) to read as follows:

§ 60.4202 What emission standards must I meet for emergency engines if I am a stationary CI internal combustion engine manufacturer?

* * * * *

(g) * * *

(1) Remote areas of Alaska; and

* * * * *

■ 4. Amend § 60.4204 by adding paragraph (f) to read as follows:

§ 60.4204 What emission standards must I meet for non-emergency engines if I am an owner or operator of a stationary CI internal combustion engine?

* * * * *

(f) Owners and operators of stationary CI ICE certified to the standards in 40 CFR part 1039 and equipped with AECDs as specified in 40 CFR 1039.665 must meet the Tier 1 certification emission standards for new nonroad CI engines in 40 CFR 89.112 while the AECD is activated during a qualified emergency situation. A qualified emergency situation is defined in 40 CFR 1039.665. When the qualified emergency situation has ended and the AECD is deactivated, the engine must resume meeting the otherwise applicable emission standard specified in this section.

■ 5. Amend § 60.4210 by adding paragraph (j) to read as follows:

§ 60.4210 What are my compliance requirements if I am a stationary CI internal combustion engine manufacturer?

* * * * *

(j) Stationary CI ICE manufacturers may equip their stationary CI internal combustion engines certified to the emission standards in 40 CFR part 1039 with AECDs for qualified emergency situations according to the requirements

of 40 CFR 1039.665. Manufacturers of stationary CI ICE equipped with AECDs as allowed by 40 CFR 1039.665 must meet all of the requirements in 40 CFR 1039.665 that apply to manufacturers. Manufacturers must provide data demonstrating that the engine complies with the Tier 1 standard in 40 CFR 89.112 when the AECD is activated when applying for certification of an engine equipped with an AECD as allowed by 40 CFR 1039.665.

■ 6. Amend § 60.4211 by adding paragraph (h) to read as follows:

§ 60.4211 What are my compliance requirements if I am an owner or operator of a stationary CI internal combustion engine?

* * * * *

(h) The requirements for operators and prohibited acts specified in 40 CFR 1039.665 apply to owners or operators of stationary CI ICE equipped with AECDs for qualified emergency situations as allowed by 40 CFR 1039.665.

■ 7. Amend § 60.4214 by adding paragraph (e) to read as follows:

§ 60.4214 What are my notification, reporting, and recordkeeping requirements if I am an owner or operator of a stationary CI internal combustion engine?

* * * * *

(e) Owners or operators of stationary CI ICE equipped with AECDs pursuant to the requirements of 40 CFR 1039.665 must report the use of AECDs as required by 40 CFR 1039.665(e).

■ 8. Amend § 60.4216 by revising paragraphs (b) through (d) and (f) as follows:

§ 60.4216 What requirements must I meet for engines used in Alaska?

* * * * *

(b) Except as indicated in paragraph (c) of this section, manufacturers, owners and operators of stationary CI ICE with a displacement of less than 10 liters per cylinder located in remote areas of Alaska may meet the requirements of this subpart by manufacturing and installing engines meeting the requirements of 40 CFR parts 94 or 1042, as appropriate, rather than the otherwise applicable requirements of 40 CFR parts 89 and 1039, as indicated in sections §§ 60.4201(f) and 60.4202(g) of this subpart.

(c) Manufacturers, owners and operators of stationary CI ICE that are located in remote areas of Alaska may choose to meet the applicable emission standards for emergency engines in §§ 60.4202 and 60.4205, and not those for non-emergency engines in §§ 60.4201 and 60.4204, except that for 2014 model year and later non-emergency CI ICE, the owner or operator of any such engine that was not certified as meeting Tier 4 p.m. standards, must meet the applicable requirements for PM in §§ 60.4201 and 60.4204 or install a PM emission control device that achieves PM emission reductions of 85 percent, or 60 percent for engines with a displacement of greater than or equal to 30 liters per cylinder, compared to engine-out emissions.

(d) The provisions of § 60.4207 do not apply to owners and operators of pre-2014 model year stationary CI ICE subject to this subpart that are located in remote areas of Alaska.

* * * * *

(f) The provisions of this section and § 60.4207 do not prevent owners and operators of stationary CI ICE subject to this subpart that are located in remote areas of Alaska from using fuels mixed with used lubricating oil, in volumes of up to 1.75 percent of the total fuel. The sulfur content of the used lubricating oil must be less than 200 parts per million. The used lubricating oil must meet the on-specification levels and properties for used oil in 40 CFR 279.11.

■ 9. Amend § 60.4219 by adding in alphabetical order the definitions for ''*Alaska Railbelt Grid*'' and ''*Remote areas of Alaska*'' to read as follows:

§ 60.4219 What definitions apply to this subpart?

* * * * *

Alaska Railbelt Grid means the service areas of the six regulated public utilities that extend from Fairbanks to Anchorage and the Kenai Peninsula. These utilities are Golden Valley Electric Association; Chugach Electric Association; Matanuska Electric Association; Homer Electric Association; Anchorage Municipal Light & Power; and the City of Seward Electric System.

* * * * *

Remote areas of Alaska means areas of Alaska that meet either paragraph (1) or (2) of this definition.

(1) Areas of Alaska that are not accessible by the Federal Aid Highway System (FAHS).

(2) Areas of Alaska that meet all of the following criteria:

(i) The only connection to the FAHS is through the Alaska Marine Highway System, or the stationary CI ICE operation is within an isolated grid in Alaska that is not connected to the statewide electrical grid referred to as the Alaska Railbelt Grid.

(ii) At least 10 percent of the power generated by the stationary CI ICE on an annual basis is used for residential purposes.

(iii) The generating capacity of the source is less than 12 megawatts, or the stationary CI ICE is used exclusively for backup power for renewable energy.

* * * * *

[FR Doc. 2015–28342 Filed 11–5–15; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 25, 73, and 74

[GN Docket No. 15–236; FCC 15–137]

Review of Foreign Ownership Policies for Broadcast, Common Carrier and Aeronautical Radio Licensees

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) proposes to extend its foreign ownership rules and procedures that apply to common carrier licensees to broadcast licensees, with certain modifications to tailor them to the broadcast context. The Commission also seeks comment on whether and how to revise the methodology a licensee should use to assess its compliance with the 25 percent foreign ownership benchmark in section 310(b)(4) of the Communications Act of 1934, as amended, in order to reduce regulatory burdens on applicants and licensees. Finally, the Commission makes several proposals to clarify and update existing foreign ownership policies and procedures for broadcast, common carrier and aeronautical licensees.

DATES: Submit comments on or before December 21, 2015, and replies on or before January 20, 2016. The NPRM contains potential information collection requirements subject to the PRA, Public Law 104–13. OMB, the general public, and other Federal agencies are invited to comment on the potential new and modified information collection requirements contained in this NPRM. If the information collection requirements are adopted, the Commission will submit the appropriate documents to OMB for review under Section 3507(d) of the PRA. OMB, the general public, and other Federal agencies will again be invited to comment on the new and modified information collection requirements adopted by the Commission.

ADDRESSES: You may submit comments, identified by Docket No. 15–236, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Federal Communications Commission's ECFS Web site: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.

• *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email to *FCC504@fcc.gov,* phone: 202–418–0530 (voice), tty: 202–418–0432.

In addition to filing comments as described above, a copy of any comments on the PRA information collection requirements contained herein should be submitted to the FCC via email to *PRA@fcc.gov* and to Nicholas A. Fraser, OMB, via email to *Nicholas_A._Fraser@omb.eop.gov* or via fax at 202–395–5167.

For detailed instructions on submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Kimberly Cook or Denise Coca, Policy Division, International Bureau, FCC, (202) 418–1460 or via email to *Kimberly.Cook@fcc.gov, Denise.Coca@fcc.gov.* On PRA matters, contact Cathy Williams, Office of the Managing Director, FCC, (202) 418–2918 or via email to *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking in GN Docket No. 15–236, FCC 15–137, adopted and released on October 22, 2015. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street SW., Washington, DC 20554. The document also is available for download over the Internet at *http://transition.fcc.gov/Daily_Releases/Daily_Business/2015/db1027/FCC-15-137A1.pdf.*

Comment Filing Procedures

Pursuant to §§ 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated above. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

• *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the Commission's ECFS Web site at *http://apps.fcc.gov/ecfs/.*

• *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

• All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.

• Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

• U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington DC 20554.

Synopsis of Notice of Proposed Rulemaking

1. The Notice of Proposed Rulemaking (NPRM) proposes to simplify the foreign ownership approval process for broadcast licensees by extending the streamlined rules and procedures developed for foreign ownership reviews for common carrier and certain aeronautical licensees under section 310(b)(4) of the Communications Act of 1934, as amended (the Act), 47 U.S.C. 310(b)(4), to the broadcast context. For ease of reference, the NPRM refers to broadcast, common carrier, aeronautical en route and aeronautical fixed radio station applicants and licensees (including broadcast permittees) and to common carrier spectrum lessees collectively as ''licensees'' unless the context warrants otherwise. The NPRM also uses the term ''common carrier'' or ''common carrier licensees'' to encompass common carrier, aeronautical en route and aeronautical fixed radio station applicants and licensees unless the context applies only to common carrier licensees. ''Spectrum lessees'' are defined in section 1.9003 of Part 1, Subpart X, 47 CFR 1.9003. The NPRM also refers to aeronautical en route and aeronautical fixed licensees collectively as ''aeronautical'' licensees. In using this shorthand, the NPRM does not include other types of aeronautical radio station licenses issued by the Commission.

2. The changes proposed in the NPRM will facilitate investment from new sources of capital at a time of growing need for capital investment in this important sector of our nation's economy. The Commission believes that adopting a standardized filing and review process for broadcast licensees' requests to exceed the 25 percent foreign ownership benchmark in section 310(b)(4), as the Commission has done for common carrier licensees, will also provide the broadcast sector with greater transparency, more predictability, and will reduce regulatory burdens and costs.

3. Specifically, the NPRM proposes to extend the foreign ownership rules and procedures established in the *2013 Foreign Ownership Second Report and Order*[1] to broadcast licensees, with certain modifications to tailor them to this context. The NPRM also seeks comment on whether and how to revise the methodology a licensee should use to assess its compliance with the 25 percent foreign ownership benchmark in section 310(b)(4) in order to reduce regulatory burdens on applicants and licensees. Finally, the NPRM makes several proposals to clarify and update existing policies and procedures for broadcast, common carrier and aeronautical licensees.

4. Section 310(b)(4) of the Act establishes a 25 percent benchmark for investment by foreign individuals, governments, and corporations in U.S.-organized entities that directly or indirectly control a U.S. broadcast, common carrier, or aeronautical radio licensee. Licensees request Commission approval of their controlling U.S. parents' foreign ownership under section 310(b)(4) by filing a petition for declaratory ruling. For the Commission to make the public interest findings required by that section of the Act, licensees file the petition and obtain Commission approval before direct or indirect foreign ownership of their U.S. parent companies exceeds 25 percent. The Commission assesses, in each particular case, whether the foreign interests presented for approval by the licensee are in the public interest, consistent with the Commission's section 310(b)(4) policy framework. The Commission's public interest analysis also considers any national security, law

[1] *Review of Foreign Ownership Policies for Common Carrier and Aeronautical Radio Licenses Under Section 310(b)(4) of the Communications Act of 1934, as Amended,* IB Docket No. 11–133, Second Report and Order, 28 FCC Rcd 5741 (2013) (*2013 Foreign Ownership Second Report and Order*).

enforcement, foreign policy or trade policy issues that may be raised by the foreign ownership. The Commission coordinates as necessary and appropriate with the relevant Executive Branch agencies and affords appropriate deference to their expertise on these issues.

5. To the extent the Commission adopts the NPRM's proposal to incorporate broadcast licensees into the regulatory framework for foreign ownership of common carrier licensees, with certain modifications applicable to broadcast licensees, the Commission proposes to codify the final rules in Part 1, subpart T, at sections 1.5000 through 1.5004, 47 CFR 1.5000–1.5004, and to remove sections 1.990 through 1.994, 47 CFR 1.990–1.994, from Part 1, subpart F. The NPRM generally refers to the rules by their current section numbers, but also refers as appropriate to the proposed rule sections.

Proposals and Other Options To Modify Current Regulatory Framework

6. In this NPRM, the Commission proposes to extend the foreign ownership rules and procedures applicable to common carrier licensees to broadcast licensees, with certain exceptions and proposed modifications. Specifically, the NPRM proposes to incorporate broadcast licensees into the Commission's rules that apply to petitions filed under section 310(b)(4) of the Act. The NPRM seeks comment on these proposals, as well as on any alternatives that commenters believe the Commission should consider. With respect to each proposal or proposed alternative, commenters should discuss, and, if possible, quantify, the likely costs and benefits of the proposal or proposed alternative.

7. In the *2013 Broadcast Clarification Order,* the Commission signaled that it might elect to create a standardized review process for broadcast licensees similar to that adopted in the common carrier context to streamline procedures.[2] The Commission's subsequent experience with the *2015 Pandora Declaratory Ruling*[3] illustrated a need for greater clarity and certainty in the foreign ownership context for broadcasters, as well as those seeking to acquire broadcast interests. The Commission believes that broadcasters can benefit from the streamlining measures that are applied to common carrier licensees that seek to exceed the 25 percent foreign ownership benchmark in section 310(b)(4). Furthermore, streamlining the Commission's filing and review processes may have the added benefit of attracting financial investment from new sources of capital for broadcasters.

8. The NPRM tentatively concludes that the considerations underlying the adoption of the foreign ownership rules applicable to section 310(b)(4) petitions for common carrier licensees are generally applicable to broadcast licensees. The Commission's experience applying these rules in the common carrier context demonstrates that the process is efficient and that filers are benefitting from the formal guidance. Moreover, the rules ensure that the Commission is able to satisfy its obligations under section 310(b) with respect to foreign ownership, while coordinating applications and petitions with the Executive Branch, as needed. The NPRM proposes to apply these principles in the broadcast context and seeks comment on this approach. Commenters are encouraged to review the proposed rules, provide comment on the application of these rules to the broadcast sector, and propose alternative approaches that would promote the public interest.

9. Significantly, under the proposed rules, a petitioner would be able to request (1) approval of up to 100 percent aggregate foreign ownership (voting and/or equity) by unnamed and future foreign investors in the controlling U.S. parent of a broadcast licensee, subject to certain conditions; (2) approval for any named foreign investor that proposes to acquire a less than 100 percent controlling interest to increase the interest to 100 percent at some time in the future; and (3) approval for any non-controlling named foreign investor to increase its voting and/or equity interest up to and including a non-controlling interest of 49.99 percent at some time in the future. Moreover, a petitioner would only need to obtain specific approval of foreign investors (*i.e.,* individuals, entities, or a ''group'' of foreign individuals or entities) that hold or would hold, directly or indirectly, more than five percent, and in certain circumstances, more than ten percent of the U.S. parent's equity and/or voting interests, or a controlling interest in the U.S. parent. The Commission will continue to coordinate as necessary and appropriate with the Executive Branch regarding all petitions for declaratory ruling filed under section 310(b).

10. The Commission believes that applying these rules to broadcast licensees in the context of section 310(b)(4) petitions will help improve access to capital from foreign investors and promote regulatory flexibility; preserve the Commission's statutory obligation, in consultation with the relevant Executive Branch agencies, to ensure that foreign ownership above the 25 percent benchmark serves the public interest; reduce uncertainty regarding the treatment of foreign investment in broadcast properties; and reduce burdens on filers by providing a streamlined, uniform process.

11. *Disclosable Interest Holders.* Section 1.991(e)–(g) of the rules requires all section 310(b) petitions for declaratory ruling regarding proposed foreign investment in a common carrier licensee to contain the name, address, citizenship and principal business(es) of any individual or entity, regardless of citizenship, that directly or indirectly holds or would hold, after effectuation of any planned ownership changes described in the petition, at least ten percent of the equity or voting interests in the controlling U.S. parent of the petitioning common carrier licensee or a controlling interest. The Commission adopted the ten percent threshold to ensure consistency with the ownership disclosure requirements that apply to most common carrier applicants under the Commission's licensing rules, while preserving a meaningful opportunity for the Executive Branch agencies to review petitions for national security, law enforcement, foreign policy, and trade policy concerns. The NPRM proposes to adopt a similar approach for broadcast licensees subject to the modifications described below.

12. Rather than adopt the ten percent disclosable threshold for broadcast licensees, the Commission proposes to require that broadcast entities disclose their ownership interests based on the current attribution rules and policies applicable to broadcast licensees. The Commission's media attribution rules seek to identify those interests in or relationships to licensees that confer on their holders a degree of influence or control such that the holders have a realistic potential to affect the programming decisions of licensees or other core operating functions. Given the distinct nature of the services provided by common carriers and broadcast stations, different attribution standards apply to these services. For example, as noted above, the ownership disclosure requirements applicable to most common carriers require the

[2] *Commission Policies and Procedures Under Section 310(b)(4) of the Communications Act, Foreign Investment in Broadcast Licensees,* MB Docket No. 13–50, Declaratory Ruling, 28 FCC Rcd 16244 (2013) (*2013 Broadcast Clarification Order*).

[3] *Pandora Radio LLC Petition for Declaratory Ruling Under Section 310(b)(4) of the Communications Act of 1934, as Amended,* MB Docket No. 14–109, Declaratory Ruling, FCC 15–52, 30 FCC Rcd 5094, 5095, ¶ 4 (2015) (*2015 Pandora Declaratory Ruling*), *recon denied,* FCC 15–129 (rel. Sept. 17, 2015).

disclosure of all ten percent interest holders (voting and equity); the broadcast attribution rules, however, generally require the attribution of individuals or entities that hold five percent or more of the voting stock, while non-voting stock interests are typically not attributable. The Commission believes that consistency with its broadcast attribution rules would ensure certainty and efficiency for broadcast firms with foreign ownership interests. Additionally, broadcast industry filers are familiar with the Commission's media attribution rules and are already required to disclose such interest holders on various Commission forms and applications (*e.g.,* FCC Form 323, Ownership Report for Commercial Broadcast Stations). Given that familiarity, the Commission believes it would pose an undue hardship to establish a different disclosure threshold for broadcasters. The NPRM seeks comment on this proposal.

13. *Specific Approval of Named Foreign Investors.* Section 1.991(i) of the rules requires a common carrier licensee filing a section 310(b)(4) petition to identify and request specific approval for any foreign individual or entity, or ''group'' of foreign individuals or entities, that holds or would hold directly, or indirectly through one or more intervening U.S.- or foreign-organized entities, more than five percent of the U.S. parent's total outstanding capital stock (equity) and/or voting stock, or a controlling interest. In addition, as a condition of the initial ruling, and with respect to any future interests that may be acquired by foreign investors, section 1.994(a)(1) similarly requires the licensee to file a new petition to obtain prior approval before any foreign individual, entity, or ''group'' not previously approved acquires a greater-than-five percent interest in the U.S. parent that does not qualify as exempt under section 1.991(i)(3). In circumstances where a foreign-organized entity requires specific approval, the petition must include the information specified in section 1.991(j), including the name and citizenship of any individual or entity that holds, or would hold, directly and/or indirectly, through one or more intervening entities, ten percent or more of the equity interests and/or voting interests, or a controlling interest, in the foreign entity for which the petitioner requests specific approval. The NPRM proposes to adopt a similar approach for broadcast licensees subject to the modifications described below.

14. Consistent with the NPRM's proposal regarding disclosable interest holders in general, the Commission does not believe that it would be appropriate to require broadcast petitioners to use the ten percent standard specified in section 1.991(j)(ii)(2) for petitions filed by common carrier. Instead, the NPRM proposes again to rely on the attribution standards set out in section 73.3555 applicable to broadcast stations to determine which individuals and entities should be listed for each foreign entity for which the broadcast licensee seeks specific approval. The Commission believes that consistency with the broadcast attribution rules and the familiarity of broadcasters with these rules support such an approach. The NPRM seeks comment on this proposal.

15. *Insulation Criteria.* For broadcast licensees, the NPRM proposes to rely on the broadcast insulation criteria set forth in the broadcast rules, rather than those applied in the common carrier context. The insulation criteria for broadcasters are governed by Note 2(f) of section 73.3555. Under the broadcast attribution rules governing partnership and limited liability company (LLC) interests, all general partners and non-insulated limited partnership and LLC interests are attributable. An exception from attribution applies only to those limited partners and LLC interest holders that meet the Commission's insulation criteria and certify that they are not materially involved in the management or operations of the entity's media interests. While there are many similarities in the insulation criteria under section 1.993 and Note 2(f) of section 73.3555, the broadcast criteria contain elements that are specific to media-related activities and reflect the distinct nature of broadcast operations.

16. The Commission believes consistency with its broadcast insulation policies under its attribution rules is appropriate to apply in the foreign ownership context. Broadcast entities are already familiar with these insulation criteria, and those entities that have insulated certain interests have already executed their organizational documents based on these criteria. Adopting different criteria in this context may require these entities to revise and re-execute their organizational documents, renegotiate the roles of insulated interest holders, and operate pursuant to multiple insulation standards when seeking approval of foreign ownership above the 25 percent benchmark in section 310(b)(4). If the Commission were to adopt different criteria, what would the costs associated with applying the common carrier foreign ownership insulation criteria be for broadcasters? Are there any public interest benefits that would exceed such costs? Are there alternative insulation criteria for broadcast entities that might be more appropriate in the context of the Commission's foreign ownership review pursuant to section 310(b)(4)? Would the benefits of imposing any alternative criteria exceed the cost of compliance? The NPRM seeks comment on these issues.

17. *Service-Specific Rulings.* Foreign ownership rulings issued to common carrier licensees cover, unless otherwise specified in a particular ruling, any common carrier radio service in any geographic location regardless of the particular wireless service(s) (*e.g.,* Personal Communications Service) and geographic service area(s) authorized under the petitioner's existing license(s). Such rulings may also be issued when an applicant seeks authority in a contemporaneously filed application for an initial license or for consent to acquire licenses by transfer or assignment. The NPRM seeks comment on whether there are considerations unique to broadcasting that suggest a different approach.

18. The Commission has noted in the past the important distinctions between common carrier services and broadcast media in the context of the public interest analysis under section 310(b)(4). For example, the Commission has noted that, while common carrier licenses are passive in nature and confer no control over the content of transmissions, broadcast transmissions have been found to present additional concerns because broadcasters exercise control over the content that they air. The Commission's approach to the benchmark for foreign investments in broadcast licensees has reflected ''heightened concern for foreign influence over or control over broadcast licensees which exercise editorial discretion over the content of their transmissions.''

19. Given these considerations, the NPRM seeks comment on how the Commission's process should be adapted, if at all, to address service-specific rulings. The foreign ownership rules that currently apply to common carrier licensees allow a ruling for such licensees that applies to all types of common carrier wireless services, *e.g.,* satellite, CMRS, microwave, AWS. In addition, the rulings are not geographic specific. Thus, a licensee does not need separate rulings to provide service in the conterminous United States and Puerto Rico. However, given the foregoing issues, a broadcast ruling may require different parameters. The NPRM seeks comment on whether the

Commission should issue rulings on a service and/or geographic basis. For example, to which services would a ruling apply? If a licensee has a ruling covering television licenses, would it need a new ruling if it later sought to acquire AM radio station licenses? Would a licensee with a ruling for an AM radio station in a small market require a new ruling if it sought to acquire a national chain of radio stations or additional stations in that small market?

20. Similar questions arise if a common carrier licensee seeks to acquire a broadcast licensee. Would a ruling for common carrier licenses apply prospectively to broadcast licenses that the licensee sought to acquire? Given that the NPRM proposes to adopt differing requirements depending on service (*e.g.,* different disclosable interest holders), how would such differences be reconciled if, for example, a common carrier ruling also were to cover the subsequent acquisition of a television station? The NPRM tentatively concludes that entities should not be required to provide the disclosable interest information for both common carrier and broadcast licensees if they propose to provide only one of those types of services, and that the Commission should conduct its public interest analysis for all services only where the applicant is to hold licenses as both common carrier and broadcaster. The NPRM seeks comment on this issue, including whether there is significant interest in the marketplace for entities with foreign ownership to hold both common carrier and broadcast licenses.

21. *Filing and Processing of Broadcast Petitions.* Section 1.990(b) of the rules provides that petitions for declaratory ruling shall be filed electronically through the International Bureau Filing System (IBFS). For broadcast petitions, however, the NPRM proposes that petitions for declaratory ruling be filed electronically as an attachment to the underlying applications for a construction permit or an assignment or transfer of control that are electronically filed through the Commission's Consolidated Database System (CDBS) or any successor database. As is the current procedure, such applications would be placed on a CDBS-generated public notice denoting that the application is ''accepted for filing.'' This public notice initiates the formal processing of the application, provides notice to interested members of the public who may wish to support or oppose the application, and triggers the legal timeframe for the filing of petitions to deny. Such a petition for declaratory ruling would separately receive a Media Bureau docket number for public notice and comment, in addition to the CDBS-generated public notice on the associated application.

22. The NPRM also proposes that, in the absence of an underlying broadcast construction permit, assignment or transfer application, the broadcast petitioner would file its petition for declaratory ruling electronically with the Commission's Office of the Secretary via the Commission's Electronic Comment Filing System (ECFS) as a non-docketed filing. The petition will subsequently receive a Media Bureau docket number and a public notice seeking comment will be released. The petition would be reviewed and, after consultation with the relevant Executive Branch agencies, a decision issued. This proposal will facilitate an efficient, predictable filing and processing scheme for broadcast petitions for declaratory ruling whether or not those petitions are accompanied by a construction permit, or an assignment or transfer application. Broadcasters are familiar with both the Commission's CDBS and ECFS filing systems and, as such, the Commission expects implementation of these filing and notice measures will provide regulatory consistency. The NPRM seeks comment on this proposal.

23. *Methodology for Assessing Compliance with Section 310(b)(4).* The NPRM proposes to adopt a rule applicable to U.S. public companies that would specify the information upon which a licensee's controlling U.S. parent may rely for purposes of determining its aggregate level of foreign ownership. Such a rule should provide greater clarity for U.S. public companies and reduce the burden of determining their aggregate levels of foreign ownership given the difficulties in ascertaining the citizenship of their shareholders. The NPRM seeks comment on adoption of such a rule, including the type of information that would likely be known to a U.S. public company in the normal course of business. The NPRM also seeks comment on specific alternative proposals to accomplish the Commission's goal of providing licensees with a more workable means of ensuring compliance with section 310(b)(4).

24. In the *2015 Pandora Declaratory Ruling* proceeding, the National Association of Broadcasters (NAB) and the Multicultural Media and Telecommunications Council (MMTC) raised concerns that the Commission's policies for calculating levels of foreign ownership in broadcast entities are ''outdated'' and should be modified to comport with current securities laws regarding widely-traded public entities. MMTC stated that broadcasters that are public companies need flexible, practical, and efficient means to estimate foreign ownership to comply with section 310(b)(4), which would attract new foreign capital that will be needed to help minority broadcasters ''overcome a severe lack of access to domestic capital.'' NAB also contended that the present policies tend to frustrate efforts to attract capital to broadcast firms. MMTC and NAB raise important issues, and the Commission stated in the *2015 Pandora Declaratory Ruling* that it would examine whether it is appropriate to revise the methodology for assessing broadcaster compliance with section 310(b)(4). These issues are not limited to broadcast licensees and also affect common carrier licensees' compliance with section 310(b)(4). Thus the NPRM seeks to address the practices used by any licensee in order to ensure compliance with section 310(b)(4). In addition, the NPRM seeks comment on whether any changes that the Commission makes regarding what licensees need to do to ensure compliance with section 310(b)(4) should also apply to ensuring compliance with section 310(b)(3).

25. NAB maintains that the Commission's compliance policies are outdated, in part, because they pertain to regulations of some 40 years ago when Securities and Exchange Commission (SEC) regulations related to physically holding stock certificates. The current practice involves holding shares of publicly traded companies in ''street name'' (*i.e.,* the broker holding legal title to a share on behalf of the beneficial owner). NAB notes that SEC rules specifically limit brokers from providing companies with shareholder information without shareholder permission, and, as such, widely-traded public entities have ''little recourse'' if the shareholder decides to remain anonymous. According to NAB, in light of current industry practices and SEC rules, the Commission cannot rationally assume that all unidentified shareholders are foreign. NAB claims that as many as 70 to 80 percent of publicly traded shares are held in street name, and that it is unlikely that the majority of shareholders are aware of, or care, if a brokerage firm holds their securities in street name.

26. Since the issuance of the *2015 Pandora Declaratory Ruling,* the Commission has further considered the regulatory hurdles to certifying compliance with foreign ownership limits and for requesting Commission

approval to exceed the statutory benchmark of 25 percent foreign ownership. In particular, the Commission notes the unique burdens its processes may exert on widely-held publicly traded companies, which do not necessarily have adequate means to ascertain and certify the citizenship of their shareholders. The Commission's aim is to provide licensees with greater flexibility in their regulatory filings and certifications.

27. The NPRM seeks comment on what steps licensees should take to track their foreign ownership to ensure compliance with section 310(b)(4). Privately-held companies, partnerships and LLCs should have knowledge of all of their owners, and should be able to track their foreign ownership relatively easily. The NPRM seeks comment on the Commission's view that privately-held entities should have knowledge of the citizenship of their owners. The NPRM also seeks comment on whether it is appropriate to adopt any measures to facilitate their ability to demonstrate compliance with section 310(b)(4), including any or all of the proposals described in this NPRM.

28. Publicly-traded companies face a more complicated challenge to demonstrate compliance with section 310 (b)(4). As NAB notes, most shares of publicly-traded companies are now held in street name and it can be difficult for the licensee to determine the citizenship of the beneficial owner of those shares. While publicly traded companies can undertake surveys of their shareholders' equity and voting interests, those surveys may not be able to ascertain the beneficial shareholders' citizenship. The Commission believes a U.S.-organized public company should, however, know, or can be expected to know, information about certain shareholders. For example, U.S.-organized public companies should know about the shareholders that are required to disclose their ownership pursuant to SEC rules—generally, those shareholders with greater than five percent ownership and institutional investors with greater than ten percent ownership. The NPRM states that the companies should also know the ownership of the shares registered with the company and the shares held by officers and directors. Are there other types of shares about which a U.S. public company could be expected to know?

29. The NPRM seeks comment on the Commission's authority to provide licensees with greater flexibility to demonstrate compliance with section 310(b)(4). The NPRM specifically seeks comment on whether it would be consistent with the Commission's obligations under section 310(b)(4) to permit a licensee with a U.S.-organized public company in its ownership chain to rely solely on ownership information that is known or reasonably should be known to the public company to determine whether the licensee is in compliance with the foreign ownership benchmark in section 310(b)(4). If the Commission adopts this proposed approach, are there policy or legal reasons to limit its availability to U.S.-organized public companies, and/or companies for which a certain percentage of their officers and directors are U.S. citizens? What amount or type of shareholder data should licensees be required to produce to satisfy their ''best efforts'' to comply with section 310(b)(4)? Should equity and voting ownership in the U.S. public company be treated the same or, for example, should there be a different, greater obligation to know the voting ownership? Additionally, should the Commission accept shareholder street addresses, alone, as a proxy for citizenship? If the Commission were to adopt such an approach, would there be circumstances under which street addresses, without more, would not be an acceptable method of certifying foreign ownership levels? Finally, the NPRM seeks comment on how frequently a company should be required to assess the extent of its foreign ownership if the Commission were to adopt this approach.

30. The NPRM also requests comment on alternatives to the Commission's proposed approach, such as the guidance provided in the *2015 Pandora Declaratory Ruling.* In that proceeding, the Commission instructed Pandora on several methods for determining and certifying its foreign citizenship levels, including making changes to organizational documents. Further, Pandora committed to certify on a biennial basis its foreign ownership levels using measures, among others: Using The Depository Trust Corporation (DTC) SEG–100 or equivalent program; monitoring shares held by current and former officers and directors; monitoring relevant SEC filings, obtaining a non-objecting beneficial owner (NOBO) list, and requesting that all NOBOs provide citizenship information; and making reasonable efforts to secure the cooperation of the relevant financial intermediaries in obtaining citizenship information. The Commission stated that, consistent with existing compliance practices, it expected Pandora Media to use sources other than shareholder mailing addresses or corporate headquarters locations.

31. The NPRM seeks comment on whether the use of street addresses, coupled with participation in SEG–100, would provide the Commission with sufficient information to discharge its public interest obligations pertaining to foreign ownership in broadcast licensees, while affording a more workable approach that may reduce the burden on publicly-traded companies. The NPRM observes that, under SEG–100, stock issuers approach DTC and request that their publicly traded securities be included in the program. DTC then updates its notations as to those requiring SEG–100 treatment and notifies all DTC participants that they must apply SEG–100 procedures to trades in the restricted company's stock. DTC participants are obligated to make inquiries of their account holders and to place the shares of such holders who are non-citizens in the DTC participant's segregated account. The NPRM asks commenters to raise any additional substantive and procedural issues that should be considered in modifying and supplementing the Commission's processes with regard to compliance with the broadcast foreign ownership rules and policies.

32. The NPRM also solicits comment on NAB's suggestion that the Commission eliminate the presumption that unidentified shareholders be counted as foreign. In light of the difficulties public companies now face in obtaining information about their domestic as well as foreign shareholders, as the record in the Pandora proceeding indicated, the Commission seeks comment on alternatives to this presumption. If the Commission were to change this presumption, should applicants be allowed to extrapolate foreign ownership percentages based on known shareholders? For example, if ten percent of the identified shares are owned by foreign owners, should the Commission presume that ten percent of the unidentified shares are held by foreign owners? Alternatively, should the Commission extrapolate using a multiple? If so, what should that multiple be? Should there be an upper limit on the relative number of unknown shareholders that can be estimated under any such approach?

33. In addition, is there a legal and policy basis for concluding in this proceeding, under section 310(b)(4), that the public interest would be served by permitting small foreign equity and/or voting interests in U.S. public companies—*e.g.,* equity or voting interests that are not required to be

reported under SEC Rule 13d–1, 17 CFR 240.13d–1,—without the Commission's individual review and approval, even in circumstances where the U.S. public company may have aggregate foreign ownership (or aggregate foreign and unknown ownership) exceeding 25 percent? If so, does that basis extend to a finding that the public interest would be served by permitting a U.S. public company to have up to an aggregate less than 50 percent (or some higher level) non-controlling foreign investment, even with individual investments that may be required to be reported under SEC Rule 13d–1, without individual review and approval? The NPRM seeks comment on these approaches and asks commenters to provide any other suggestions.

34. *Corrections and Clarifications of Existing Rules.* The Commission takes this opportunity to make certain technical corrections to the foreign ownership rules and seeks comment on proposed clarifying changes, as well as on any other changes commenters may suggest to improve the structure and clarity of the rules.

35. First, in section 1.5001 of the proposed rules, which lists the required contents of petitions for declaratory ruling, the NPRM proposes to include a cross-reference to section 1.5000(c), the requirement that each applicant, licensee, or spectrum lessee filing a section 310(b) petition for declaratory ruling certify to the information contained in the petition in accordance with the provisions of section 1.16 of the rules. The Commission has found that it is not uncommon for petitions to be filed without the required certification. The NPRM therefore includes in proposed rule section 1.5001(l) a cross-reference to the certification requirement to highlight to filers this critical aspect of the rules.

36. Second, the NPRM proposes to include two Notes in section 1.5001(i) of the proposed rules to clarify that certain foreign interests of five percent or less may require specific approval in circumstances where there is direct or indirect foreign investment in the U.S. parent in the form of uninsulated partnership interests or uninsulated interests held by members of an LLC. Many limited partners and LLC members hold small equity interests in their respective companies with control of these companies residing in the general partner or managing member, respectively. However, for purposes of identifying foreign interests that require specific approval (and for determining a common carrier licensee's disclosable U.S. and foreign interest holders), uninsulated partners and uninsulated LLC members are deemed to hold the same *voting* interest as the partnership or LLC holds in the company situated in the next lower tier of the licensee's vertical ownership chain. Depending on the particular ownership structure presented in the petition, an uninsulated foreign limited partner or uninsulated LLC member may require specific approval because the voting interest it is deemed to hold in the U.S. parent exceeds five percent and, because it is an uninsulated voting interest, it does not qualify as exempt from the specific approval requirements. The NPRM requests comment on the proposed language and placement of these Notes, which are intended to improve the clarity of the specific approval requirements as recodified in section 1.5001(i) of the rules.

37. Third, the NPRM seeks comment on whether Commission precedent supports the inclusion of additional permissible voting or consent rights in the list of investor protections where the rights do not, in themselves, result in a limited partnership or LLC interest being deemed uninsulated within the meaning of that section. Similarly, the NPRM requests comment on whether Commission precedent supports the inclusion of additional permissible minority shareholder protections.

38. Finally, the NPRM proposes to correct two cross-references, and to make additional clarifying changes.

39. *Transition Issues.* Consistent with the approach adopted in the *2013 Foreign Ownership Second Report and Order,* the NPRM proposes that any changes adopted in this proceeding be applied prospectively. The NPRM proposes that existing foreign ownership rulings issued prior to the effective date of the rules adopted in this proceeding shall remain in effect. Specifically, as is currently the case under the Commission's foreign ownership rules for common carrier licensees, licensees subject to an existing ruling as of the effective date of the rules adopted in this proceeding would be required to continue to comply with any general and specific terms and conditions of their rulings, including Commission rules and policies in effect at the time the ruling was issued. The NPRM proposes that such licensees may, however, request a new ruling under any revised rules, but they are not required to do so. The NPRM tentatively concludes that this approach is appropriate because it will afford the Commission and the relevant Executive Branch agencies an opportunity to evaluate the potential effects of applying the new rules to licensees that are subject to an existing ruling. The NPRM seeks comment on this approach and on how to treat any requests for declaratory ruling that are pending before the Commission as of the effective date of the rules adopted in this proceeding. Should the Commission review these requests under the rules adopted in this proceeding? Are there other transition issues that the Commission should address?

40. The NPRM reminds common carrier licensees with an existing foreign ownership ruling of their obligation to seek a new ruling *before* they exceed the parameters of their rulings, including those rulings issued prior to August 9, 2013, the effective date of the rules adopted in the *2013 Foreign Ownership Second Report and Order.* The NPRM notes, in particular, that a licensee's ruling issued prior to August 9, 2013, may be limited in scope to the particular wireless service(s) and geographic service area(s) of the licenses or spectrum leasing arrangements referenced in the petition for declaratory ruling. The Commission's decision in the *2013 Foreign Ownership Second Report and Order* to eliminate its practice of issuing rulings on a service- and geographic-specific basis did not apply retroactively to rulings issued prior to the effective date of the rules adopted in that proceeding. Failure to meet a condition of a foreign ownership ruling may result in monetary sanctions or other enforcement action by the Commission.

41. *Other Reforms to Foreign Ownership Review.* Finally, the NPRM invites comment on any additional reforms that could further streamline Commission review of foreign ownership and bring its foreign and domestic investment review processes into closer alignment, while ensuring that important national security, law enforcement, foreign policy, trade policy and other public policy goals continue to be met. For example, are there certain types of applications that could be reviewed in a more streamlined manner than the proposals outlined in the NPRM? The Commission seeks comment on these and any other proposals that would streamline its process for analyzing foreign ownership under section 310(b)(4), while also serving its public interest goals.

Initial Paperwork Reduction Act of 1995 Analysis

42. This document contains proposed new and modified information collection requirements. The Commission, as a part of its continuing effort to reduce paperwork burdens, invites the general public and the Office

of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

Initial Regulatory Flexibility Analysis

43. The Regulatory Flexibility Act of 1980, as amended (RFA),[4] requires that an initial regulatory flexibility analysis be prepared for notice-and-comment rule making proceedings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' [5] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' [6] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[7] A ''small business concern'' is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).

44. In the NPRM, the Commission seeks comment on proposed changes and other options to incorporate broadcast licenses into the Commission's rules and procedures for analyzing foreign ownership of common carrier and aeronautical radio licensees under section 310(b)(4) of the Act, 47 U.S.C. 310(b)(4), and to clarify certain aspects of those rules and procedures for broadcast, common carrier and aeronautical licensees while continuing to ensure that the Commission has the information it needs to carry out its statutory duties. The proposals in the NPRM are designed to reduce to the extent possible the regulatory costs and burdens imposed on broadcast, wireless common carrier and aeronautical applicants, licensees, and spectrum lessees; provide greater transparency and more predictability with respect to the Commission's filing requirements and review process; and facilitate investment from new sources of capital, while continuing to protect important interests related to national security, law enforcement, foreign policy, and trade policy.

45. The Commission estimates that the rule changes discussed in the NPRM, if adopted, would result in a reduction in the time and expense associated with filing section 310(b)(4) petitions for declaratory ruling by broadcast licensees. For example, the NPRM proposes that U.S. parent companies of broadcast licensees that seek Commission approval to exceed the 25 percent foreign ownership benchmark in section 310(b)(4) include in their petitions requests for specific approval only of foreign investors that would hold a direct or indirect equity and/or voting interest in the U.S. parent that exceeds five percent (or exceeds ten percent in certain circumstances), or a controlling interest. Another proposal would, if adopted, allow the U.S. parent to request specific approval for any non-controlling foreign investors named in the section 310(b)(4) petition to increase their direct or indirect equity and/or voting interests in the U.S. parent at any time after issuance of the section 310(b)(4) ruling, up to and including a non-controlling 49.99 percent equity and/or voting interest. Similarly, the U.S. parent would be permitted to request specific approval for any named foreign investor that proposed to acquire a controlling interest of less than 100 percent to increase the interest to 100 percent at some future time. The NPRM also seeks comment on measures the Commission can take to reduce the costs and burdens associated with licensees' efforts to ensure that they remain in compliance with the statutory foreign ownership requirements, which apply broadly to broadcast, common carrier, aeronautical en route and aeronautical fixed radio licensees.

46. The Commission believes that the streamlining proposals and other options on which the Commission seeks comment in the NPRM will reduce costs and burdens currently imposed on licensees, including those licensees that are small entities, and accelerate the foreign ownership review process, while continuing to ensure that the Commission has the information it needs to carry out its statutory duties. Therefore, the Commission certifies that the proposals in the NPRM, if adopted, will not have a significant economic impact on a substantial number of small entities.[8] The Commission will send a copy of the NPRM, including a copy of this Initial Regulatory Flexibility Certification, to the Chief Counsel for Advocacy of the SBA.[9] This initial certification will also be published in the **Federal Register**.[10]

Ordering Clauses

47. *It is ordered* that, pursuant to the authority contained in 47 U.S.C. Sections 151, 152, 154(i), 154(j), 211, 303(r), 309, 310 and 403, this Notice of Proposed Rulemaking is *adopted.*

48. *It is further ordered* that *notice is hereby given* of the proposed regulatory changes to Commission policy and rules described in this Notice of Proposed Rulemaking and that comment is sought on these proposals.

49. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Certification, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Parts 1, 25, 73 and 74

Communications common carriers, Radio, Reporting and recordkeeping requirements, Satellites, Telecommunications, Television.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR parts 1, 25, 73, and 74 as follows:

PART 1—PRACTICE AND PROCEDURE

■ 1. The authority citation for part 1 is revised to read as follows:

[4] *See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. 104–121, Title II, 110 Stat. 857 (1996).

[5] 5 U.S.C. 605(b).

[6] 5 U.S.C. 601(6).

[7] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.''

[8] In the proceeding in which sections 1.990–1.994 were adopted, the Commission certified that the rules and procedures for analyzing foreign ownership of common carrier and aeronautical radio licensees under section 310(b)(4), which this NPRM proposes to apply with certain modifications to broadcast licensees, would not have a significant economic impact on a substantial number of small entities. *See 2013 Foreign Ownership Second Report and Order,* 25 FCC Rcd at 5813–15; *2011 Foreign Ownership NPRM,* 26 FCC Rcd 11703, 11742–44 (2011).

[9] 5 U.S.C. 605(b).

[10] *Id.*

Authority: 15 U.S.C. 79, *et seq.;* 47 U.S.C. 151, 154(i), 154(j), 155, 157, 160, 201, 225, 227, 303, 309, 310, 332, 1403, 1404, 1451, 1452, and 1455.

§§ 1.990 through 1.994 [Removed]

■ 2. In Subpart F, remove the undesignated center heading ''Foreign Ownership of Common Carrier, Aeronautical En Route, and Aeronautical Fixed Radio Station Licensees'' and §§ 1.990 through 1.994.

■ 3. Add subpart T to read as follows:

Subpart T—Foreign Ownership of Broadcast, Common Carrier, Aeronautical En Route, and Aeronautical Fixed Radio Station Licensees

Sec.

§ 1.5000 Citizenship and filing requirements under section 310(b) of the Communications Act of 1934, as amended.

The rules in this subpart establish the requirements and conditions for obtaining the Commission's prior approval of foreign ownership in broadcast, common carrier, aeronautical en route, and aeronautical fixed radio station licensees and common carrier spectrum lessees that would exceed the 25 percent benchmark in section 310(b)(4) of the Act. These rules also establish the requirements and conditions for obtaining the Commission's prior approval of foreign ownership in common carrier (but not broadcast, aeronautical en route or aeronautical fixed) radio station licensees and spectrum lessees that would exceed the 20 percent limit in section 310(b)(3) of the Act.

(a)(1) A broadcast, common carrier, aeronautical en route or aeronautical fixed radio station licensee or common carrier spectrum lessee shall file a petition for declaratory ruling to obtain Commission approval under section 310(b)(4) of the Act, and obtain such approval, *before* the aggregate foreign ownership of any controlling, U.S.-organized parent company exceeds, directly and/or indirectly, 25 percent of the U.S. parent's equity interests and/or 25 percent of its voting interests. An applicant for a broadcast, common carrier, aeronautical en route or aeronautical fixed radio station license or common carrier spectrum leasing arrangement shall file the petition for declaratory ruling required by this paragraph at the same time that it files its application.

(2) A common carrier radio station licensee or spectrum lessee shall file a petition for declaratory ruling to obtain approval under the Commission's section 310(b)(3) forbearance approach, and obtain such approval, *before* aggregate foreign ownership, held through one or more intervening U.S.-organized entities that hold non-controlling equity and/or voting interests in the licensee, along with any foreign interests held directly in the licensee or spectrum lessee, exceeds 20 percent of its equity interests and/or 20 percent of its voting interests. An applicant for a common carrier radio station license or spectrum leasing arrangement shall file the petition for declaratory ruling required by this paragraph at the same time that it files its application. Foreign interests held directly in a licensee or spectrum lessee, or other than through U.S.-organized entities that hold non-controlling equity and/or voting interests in the licensee or spectrum lessee, shall not be permitted to exceed 20 percent.

Note 1 to paragraph (a): For purposes of calculating its foreign ownership to determine whether it is required to file a petition for declaratory ruling under paragraph (a)(1) or (2) of this section, a U.S.-organized publicly-traded company shall use information about its voting and non-voting stock available to it in the normal course of business, including ownership information required to be disclosed pursuant to rules of the Securities and Exchange Commission, shares recorded in the company's shareholder register, shares held by the members of the company's Board of Directors and shares held by its officers. A U.S.-organized publicly-traded company is a company: That is organized in the United States; whose stock is traded on a stock exchange in the United States; that is headquartered in the United States; with a majority of members of its Board of Directors who are citizens of the United States; and with a majority of officers who are citizens of the United States.

Note 2 to paragraph (a): Paragraph (a)(1) of this section implements the Commission's foreign ownership policies under section 310(b)(4) of the Act, 47 U.S.C. 310(b)(4), for broadcast, common carrier, aeronautical en route, and aeronautical fixed radio station licensees and common carrier spectrum lessees. It applies to foreign equity and/or voting interests that are held, or would be held, directly and/or indirectly in a U.S.-organized entity that itself directly or indirectly *controls* a broadcast, common carrier, aeronautical en route, or aeronautical fixed radio station licensee or common carrier spectrum lessee. A foreign individual or entity that seeks to hold a controlling interest in such a licensee or spectrum lessee must hold its controlling interest indirectly, in a U.S.-organized entity that itself directly or indirectly controls the licensee or spectrum lessee. Such controlling interests are subject to section 310(b)(4) and the requirements of paragraph (a)(1) of this section. The Commission assesses foreign ownership interests subject to section 310(b)(4) separately from foreign ownership interests subject to section 310(b)(3).

Note 3 to paragraph (a): Paragraph (a)(2) of this section implements the Commission's section 310(b)(3) forbearance approach adopted in the First Report and Order in IB Docket No. 11–133, FCC 12–93 (released August 17, 2012), 77 FR 50628 (Aug. 22, 2012). The section 310(b)(3) forbearance approach applies only to foreign equity and voting interests that are held, or would be held, in a common carrier licensee or spectrum lessee through one or more intervening U.S.-organized entities that *do not control* the licensee or spectrum lessee. Foreign equity and/or voting interests that are held, or would be held, directly in a licensee or spectrum lessee, or indirectly other than through an intervening U.S.-organized entity, are not subject to the Commission's section 310(b)(3) forbearance approach and shall not be permitted to exceed the 20 percent limit in section 310(b)(3) of the Act, 47 U.S.C. 310(b)(3). The Commission's forbearance approach does not apply to broadcast, aeronautical en route or aeronautical fixed radio station licenses.

Example 1. U.S.-organized Corporation A is preparing an application to acquire a common carrier radio license by assignment from another licensee. U.S.-organized Corporation A is wholly owned and controlled by U.S.-organized Corporation B. U.S.-organized Corporation B is 51 percent owned and controlled by U.S.-organized Corporation C, which is, in turn, wholly owned and controlled by foreign-organized Corporation D. The remaining non-controlling 49 percent equity and voting interests in U.S.-organized Corporation B are held by U.S.-organized Corporation X, which is, in turn, wholly owned and controlled by U.S. citizens. Paragraph (a)(1) of this section requires that U.S.-organized Corporation A file a petition for declaratory ruling to obtain Commission approval of the 51 percent foreign ownership of its controlling, U.S.-organized parent, Corporation B, by foreign-organized Corporation D, which exceeds the 25 percent benchmark in section 310(b)(4) of the Act for both equity interests and voting interests. Corporation A is also required to identify and request specific approval in its petition for any foreign individual or entity, or ''group,'' as defined in paragraph (d) of this section, that holds directly and/or indirectly more than five percent of Corporation B's total outstanding capital stock (equity) and/or voting stock, or a controlling interest in Corporation B, unless the foreign investment is exempt under § 1.5001(i)(3).

Example 2. U.S.-organized Corporation A is preparing an application to acquire a common carrier radio license by assignment from another licensee. U.S.-organized Corporation A is 51 percent owned and controlled by U.S.-organized Corporation B, which is, in turn, wholly owned and controlled by U.S. citizens. The remaining non-controlling 49 percent equity and voting interests in U.S.-organized Corporation A are held by U.S.-organized Corporation X, which is, in turn, wholly owned and controlled by foreign-organized Corporation Y. Paragraph (a)(2) of this section requires that U.S.-organized Corporation A file a petition for declaratory ruling to obtain Commission approval of the non-controlling 49 percent foreign ownership of U.S.-organized Corporation A by foreign-organized Corporation Y through U.S.-organized Corporation X, which exceeds the 20 percent limit in section 310(b)(3) of the Act for both equity interests and voting interests. U.S.-organized Corporation A is also required to identify and request specific approval in its petition for any foreign individual or entity, or ''group,'' as defined in paragraph (d) of this section, that holds an equity and/or voting interest in foreign-organized Corporation Y that, when multiplied by 49 percent, would exceed five percent of U.S.-organized Corporation A's equity and/or voting interests, unless the foreign investment is exempt under § 1.5001(i)(3).

Example 3. U.S.-organized Corporation A is preparing an application to acquire a common carrier radio license by assignment from another licensee. U.S.-organized Corporation A is 51 percent owned and controlled by U.S.-organized Corporation B, which is, in turn, wholly owned and controlled by foreign-organized Corporation C. The remaining non-controlling 49 percent equity and voting interests in U.S.-organized Corporation A are held by U.S.-organized Corporation X, which is, in turn, wholly owned and controlled by foreign-organized Corporation Y. Paragraphs (a)(1) and (a)(2) of this section require that U.S.-organized Corporation A file a petition for declaratory ruling to obtain Commission approval of foreign-organized Corporation C's 100 percent ownership interest in U.S.-organized parent, Corporation B, and of foreign-organized Corporation Y's non-controlling, 49 percent foreign ownership interest in U.S.-organized Corporation A through U.S-organized Corporation X, which exceed the 25 percent benchmark and 20 percent limit in sections 310(b)(4) and 310(b)(3) of the Act, respectively, for both equity interests and voting interests. U.S-organized Corporation A's petition also must identify and request specific approval for ownership interests held by any foreign individual, entity, or ''group,'' as defined in paragraph (d) of this section, to the extent required by § 1.5001(i).

(b) Except for petitions involving broadcast stations only, the petition for declaratory ruling required by paragraph (a) of this section shall be filed electronically on the Internet through the International Bureau Filing System (IBFS). For information on filing your petition through IBFS, see part 1, subpart Y and the IBFS homepage at *http://www.fcc.gov/ib.* Petitions for declaratory ruling required by paragraph (a) of this section involving broadcast stations only shall be filed electronically on the Internet through the Media Bureau's Consolidated Database System (CDBS) or any successor system thereto when submitted to the Commission as part of an application for a construction permit, assignment, or transfer of control of a broadcast license; if there is no associated construction permit, assignment or transfer of control application, petitions for declaratory ruling should be filed with the Office of the Secretary via the Commission's Electronic Comment Filing System (ECFS).

(c)(1) Each applicant, licensee, or spectrum lessee filing a petition for declaratory ruling required by paragraph (a) of this section shall certify to the information contained in the petition in accordance with the provisions of § 1.16 and the requirements of this paragraph. The certification shall include a statement that the applicant, licensee and/or spectrum lessee has calculated the ownership interests disclosed in its petition based upon its review of the Commission's rules and that the interests disclosed satisfy each of the pertinent standards and criteria set forth in the rules.

(2) Multiple applicants and/or licensees shall file *jointly* the petition for declaratory ruling required by paragraph (a) of this section where the entities are under common control and contemporaneously hold, or are contemporaneously filing applications for, broadcast, common carrier licenses, common carrier spectrum leasing arrangements, or aeronautical en route or aeronautical fixed radio station licenses. Where joint petitioners have different responses to the information required by § 1.5001, such information should be set out separately for each joint petitioner, except as otherwise permitted in § 1.5001(h)(2).

(i) Each joint petitioner shall certify to the information contained in the petition in accordance with the provisions of § 1.16 with respect to the information that is pertinent to that petitioner. Alternatively, the controlling parent of the joint petitioners may certify to the information contained in the petition.

(ii) Where the petition is being filed in connection with an application for consent to transfer control of licenses or spectrum leasing arrangements, the transferee or its ultimate controlling parent may file the petition on behalf of the licensees or spectrum lessees that would be acquired as a result of the proposed transfer of control and certify to the information contained in the petition.

(3) Multiple applicants and licensees shall not be permitted to file a petition for declaratory ruling jointly unless they are under common control.

(d) The following definitions shall apply to this section and §§ 1.5001 through 1.5004.

(1) *Aeronautical radio* licenses refers to aeronautical en route and aeronautical fixed radio station licenses only. It does not refer to other types of aeronautical radio station licenses.

(2) *Affiliate* refers to any entity that is under common control with a licensee, defined by reference to the holder, directly and/or indirectly, of more than 50 percent of total voting power, where no other individual or entity has *de facto* control.

(3) *Control* includes actual working control in whatever manner exercised and is not limited to majority stock ownership. *Control* also includes direct or indirect control, such as through intervening subsidiaries.

(4) *Entity* includes a partnership, association, estate, trust, corporation, limited liability company, governmental authority or other organization.

(5) *Group* refers to two or more individuals or entities that have agreed to act together for the purpose of acquiring, holding, voting, or disposing of their equity and/or voting interests in the relevant licensee, controlling U.S. parent, or entity holding a direct and/or indirect equity and/or voting interest in the licensee or U.S. parent.

(6) *Individual* refers to a natural person as distinguished from a partnership, association, corporation, or other organization.

(7) *Licensee* as used in §§ 1.5000 through 1.5004 of this part includes a *spectrum lessee* as defined in § 1.9003.

(8) *Privately held* company refers to a U.S.- or foreign-organized company that has not issued a class of equity securities for which beneficial ownership reporting is required by security holders and other beneficial owners under sections 13(d) or 13(g) of the Securities Exchange Act of 1934, as amended, 15 U.S.C. 78a *et seq.* (Exchange Act), and corresponding Exchange Act Rule 13d–1, 17 CFR 240.13d–1, or a substantially comparable foreign law or regulation.

(9) *Public company* refers to a U.S.- or foreign-organized company that has issued a class of equity securities for which beneficial ownership reporting is required by security holders and other beneficial owners under sections 13(d) or 13(g) of the Securities Exchange Act of 1934, as amended, 15 U.S.C. 78a *et*

seq. (Exchange Act) and corresponding Exchange Act Rule 13d–1, 17 CFR 240.13d–1, or a substantially comparable foreign law or regulation.

(10) *Subsidiary* refers to any entity in which a licensee owns or controls, directly and/or indirectly, more than 50 percent of the total voting power of the outstanding voting stock of the entity, where no other individual or entity has *de facto* control.

(11) *Voting stock* refers to an entity's corporate stock, partnership or membership interests, or other equivalents of corporate stock that, under ordinary circumstances, entitles the holders thereof to elect the entity's board of directors, management committee, or other equivalent of a corporate board of directors.

(12) *Would hold* as used in §§ 1.5000 through 1.5004 includes interests that an individual or entity proposes to hold in an applicant, licensee, or spectrum lessee, or their controlling U.S. parent, upon consummation of any transactions described in the petition for declaratory ruling filed under § 1.5000(a)(1) or (2) of this part.

§ 1.5001 Contents of petitions for declaratory ruling under section 310(b) of the Communications Act of 1934, as amended.

The petition for declaratory ruling required by § 1.5000(a)(1) and/or (2) shall contain the following information:

(a) With respect to each petitioning applicant or licensee, provide its name; FCC Registration Number (FRN); mailing address; place of organization; telephone number; facsimile number (if available); electronic mail address (if available); type of business organization (*e.g.,* corporation, unincorporated association, trust, general partnership, limited partnership, limited liability company, trust, other (include description of legal entity)); name and title of officer certifying to the information contained in the petition.

(b) If the petitioning applicant or licensee is represented by a third party (*e.g.,* legal counsel), specify that individual's name, the name of the firm or company, mailing address and telephone number/electronic mail address.

(c)(1) For each named licensee, list the type(s) of radio service authorized (*e.g.,* broadcast service, cellular radio telephone service; microwave radio service; mobile satellite service; aeronautical fixed service). In the case of broadcast licensees, also list the call sign, facility identification number (if applicable), and community of license or transmit site for each authorization covered by the petition.

(2) If the petition is filed in connection with an application for a radio station license or a spectrum leasing arrangement, or an application to acquire a license or spectrum leasing arrangement by assignment or transfer of control, specify for each named applicant:

(i) The File No(s). of the associated application(s), if available at the time the petition is filed; otherwise, specify the anticipated filing date for each application; and

(ii) The type(s) of radio services covered by each application (*e.g.,* broadcast service, cellular radio telephone service; microwave radio service; mobile satellite service; aeronautical fixed service).

(d) With respect to each petitioner, include a statement as to whether the petitioner is requesting a declaratory ruling under § 1.5000(a)(1) and/or (2).

(e) *Disclosable interest holdersÐ direct U.S. or foreign interests in the controlling U.S. parent.* Paragraphs (e)(1) through (e)(4) of this section apply only to petitions filed under § 1.5000(a)(1) and/or (2) for common carrier, aeronautical en route, and aeronautical fixed radio station applicants or licensees, as applicable. Petitions filed under § 1.5000(a)(1) for broadcast licensees shall provide the name of any individual or entity that holds, or would hold, *directly,* an attributable interest in the controlling U.S. parent of the petitioning broadcast station applicant(s) or licensee(s), as defined in the Notes to § 73.3555 of this chapter. Where no individual or entity holds, or would hold, *directly,* an attributable interest in the controlling U.S. parent (for petitions filed under § 1.5000(a)(1)), the petition shall specify that no individual or entity holds, or would hold, *directly,* an attributable interest in the U.S. parent, applicant(s), or licensee(s).

(1) *Direct U.S. or foreign interests of ten percent or more or a controlling interest.* With respect to petitions filed under § 1.5000(a)(1), provide the name of any individual or entity that holds, or would hold, *directly* 10 percent or more of the equity interests and/or voting interests, or a controlling interest, in the controlling U.S. parent of the petitioning common carrier or aeronautical radio station applicant(s) or licensee(s) as specified in paragraphs (e)(4)(i) through (iv) of this section.

(2) *Direct U.S. or foreign interests of ten percent or more or a controlling interest.* With respect to petitions filed under § 1.5000(a)(2), provide the name of any individual or entity that holds, or would hold, *directly* 10 percent or more of the equity interests and/or voting interests, or a controlling interest, in each petitioning common carrier applicant or licensee as specified in paragraphs (e)(4)(i) through (iv) of this section.

(3) Where no individual or entity holds, or would hold, *directly* 10 percent or more of the equity interests and/or voting interests, or a controlling interest, in the controlling U.S. parent (for petitions filed under § 1.5000(a)(1)) or in the applicant or licensee (for petitions filed under § 1.5000(a)(2)), the petition shall state that no individual or entity holds or would hold *directly* 10 percent or more of the equity interests and/or voting interests, or a controlling interest, in the U.S. parent, applicant or licensee.

(4)(i) Where a named U.S. parent, applicant, or licensee is organized as a corporation, provide the name of any individual or entity that holds, or would hold, 10 percent or more of the outstanding capital stock and/or voting stock, or a controlling interest.

(ii) Where a named U.S. parent, applicant, or licensee is organized as a general partnership, provide the names of the partnership's constituent general partners.

(iii) Where a named U.S. parent, applicant, or licensee is organized as a limited partnership or limited liability partnership, provide the name(s) of the general partner(s) (in the case of a limited partnership), any uninsulated partner(s), and any insulated partner(s) with an equity interest in the partnership of at least 10 percent (calculated according to the percentage of the partner's capital contribution). With respect to each named partner (other than a named general partner), the petitioner shall state whether the partnership interest is insulated or uninsulated, based on the insulation criteria specified in § 1.5003.

(iv) Where a named U.S. parent, applicant, or licensee is organized as a limited liability company, provide the name(s) of each uninsulated member, regardless of its equity interest, any insulated member with an equity interest of at least 10 percent (calculated according to the percentage of its capital contribution), and any non-equity manager(s). With respect to each named member, the petitioner shall state whether the interest is insulated or uninsulated, based on the insulation criteria specified in § 1.5003, and whether the member is a manager.

Note to paragraph (e): The Commission presumes that a general partner of a general partnership or limited partnership has a controlling interest in the partnership. A general partner shall in all cases be deemed

to hold an uninsulated interest in the partnership.

(f) *Disclosable interest holdersÐ indirect U.S. or foreign interests in the controlling U.S. parent.* Paragraphs (f)(1) through (3) of this section apply only to petitions filed under § 1.5000(a)(1) and/or § 1.5000(a)(2) for common carrier, aeronautical en route, and aeronautical fixed radio station applicants or licensees, as applicable. Petitions filed under § 1.5000(a)(1) for broadcast licensees shall provide the name of any individual or entity that holds, or would hold, *indirectly,* an attributable interest in the controlling U.S. parent of the petitioning broadcast station applicant(s) or licensee(s), as defined in the Notes to § 73.3555 of this chapter. Where no individual or entity holds, or would hold, *indirectly,* an attributable interest in the controlling U.S. parent (for petitions filed under § 1.5000(a)(1)), the petition shall specify that no individual or entity holds, or would hold, *indirectly,* an attributable interest in the U.S. parent, applicant(s), or licensee(s).

(1) *Indirect U.S. or foreign interests of ten percent or more or a controlling interest.* With respect to petitions filed under § 1.5000(a)(1), provide the name of any individual or entity that holds, or would hold, *indirectly,* through one or more intervening entities, 10 percent or more of the equity interests and/or voting interests, or a controlling interest, in the controlling U.S. parent of the petitioning common carrier or aeronautical radio station applicant(s) or licensee(s). Equity interests and voting interests held indirectly shall be calculated in accordance with the principles set forth in § 1.5002.

(2) *Indirect U.S. or foreign interests of ten percent or more or a controlling interest.* With respect to petitions filed under § 1.5000(a)(2), provide the name of any individual or entity that holds, or would hold, *indirectly,* through one or more intervening entities, 10 percent or more of the equity interests and/or voting interests, or a controlling interest, in the petitioning common carrier radio station applicant(s) or licensee(s). Equity interests and voting interests held indirectly shall be calculated in accordance with the principles set forth in § 1.5002.

(3) Where no individual or entity holds, or would hold, *indirectly* 10 percent or more of the equity interests and/or voting interests, or a controlling interest, in the controlling U.S. parent (for petitions filed under § 1.5000(a)(1)) or in the petitioning applicant(s) or licensee(s) (for petitions filed under § 1.5000(a)(2)), the petition shall specify that no individual or entity holds *indirectly* 10 percent or more of the equity interests and/or voting interests, or a controlling interest, in the U.S. parent, applicant(s), or licensee(s).

Note to paragraph (f): The Commission presumes that a general partner of a general partnership or limited partnership has a controlling interest in the partnership. A general partner shall in all cases be deemed to hold an uninsulated interest in the partnership.

(g)(1) *Citizenship and other information for disclosable interests in common carrier, aeronautical en route, and aeronautical fixed radio station applicants and licensees.* For each 10 percent interest holder named in response to paragraphs (e) and (f) of this section, specify the equity interest held and the voting interest held (each to the nearest one percent); in the case of an individual, his or her citizenship; and in the case of a business organization, its place of organization, type of business organization (*e.g.,* corporation, unincorporated association, trust, general partnership, limited partnership, limited liability company, trust, other (include description of legal entity)), and principal business(es).

(2) *Citizenship and other information for attributable interests in broadcast station applicants and licensees.* For each attributable interest holder named in response to paragraphs (e) and (f) of this section, describe the nature of the attributable interest and, if applicable, specify the equity interest held and the voting interest held (each to the nearest one percent); in the case of an individual, his or her citizenship; and in the case of a business organization, its place of organization, type of business organization (*e.g.,* corporation, unincorporated association, trust, general partnership, limited partnership, limited liability company, trust, other (include description of legal entity)), and principal business(es).

(h)(1) *Estimate of aggregate foreign ownership.* For petitions filed under § 1.5000(a)(1), attach an exhibit that provides a percentage estimate of the controlling U.S. parent's aggregate direct and/or indirect foreign equity interests and its aggregate direct and/or indirect foreign voting interests. For petitions filed under § 1.5000(a)(2), attach an exhibit that provides a percentage estimate of the aggregate foreign equity interests and aggregate foreign voting interests held directly in the petitioning applicant(s) and/or licensee(s), if any, and the aggregate foreign equity interests and aggregate foreign voting interests held indirectly in the petitioning applicant(s) and/or licensee(s). The exhibit required by this paragraph must also provide a general description of the methods used to determine the percentages; and a statement addressing the circumstances that prompted the filing of the petition and demonstrating that the public interest would be served by grant of the petition.

(2) *Ownership and control structure.* Attach an exhibit that describes the ownership and control structure of the applicant(s) and/or licensee(s) that are the subject of the petition, including an ownership diagram and identification of the real party-in-interest disclosed in any companion applications. The ownership diagram should illustrate the petitioner's vertical ownership structure, including the controlling U.S. parent named in the petition (for petitions filed under § 1.5000(a)(1)) and either

(i) For common carrier, aeronautical en route, and aeronautical fixed radio station applicants and licensees, the direct and indirect ownership (equity and voting) interests held by the individual(s) and/or entity(ies) named in response to paragraphs (e) and (f) of this section; or

(ii) For broadcast station applicants and licensees, the attributable interest holders named in response to paragraphs (e) and (f) of this section. Each such individual or entity shall be depicted in the ownership diagram and all controlling interests labeled as such. Where the petition includes multiple petitioners, the ownership of all petitioners may be depicted in a single ownership diagram or in multiple diagrams.

(i) *Requests for specific approval.* Provide, as required or permitted by this paragraph, the name of each foreign individual and/or entity for which each petitioner requests specific approval, if any, and the respective percentages of equity and/or voting interests (to the nearest one percent) that each such foreign individual or entity holds, or would hold, directly and/or indirectly, in the controlling U.S. parent of the petitioning broadcast, common carrier or aeronautical radio station applicant(s) or licensee(s) for petitions filed under § 1.5000(a)(1), and in each petitioning common carrier applicant or licensee for petitions filed under § 1.5000(a)(2).

(1) Each petitioning broadcast, common carrier or aeronautical radio station applicant or licensee filing under § 1.5000(a)(1) shall identify and request specific approval for any foreign individual, entity, or group of such individuals or entities that holds, or would hold, directly and/or indirectly, more than 5 percent of the equity and/or voting interests, or a controlling

interest, in the petitioner's controlling U.S. parent unless the foreign investment is exempt under paragraph (i)(3) of this section. Equity and voting interests shall be calculated in accordance with the principles set forth in paragraphs (e) and (f) of this section and in § 1.5002.

Note to paragraph (i)(1): Solely for the purpose of identifying foreign interests that require specific approval under this paragraph (i), broadcast station applicants and licensees filing petitions under § 1.5000(a)(1) should calculate equity and voting interests in accordance with the principles set forth in paragraphs (e) and (f) of this section and in § 1.5002 and *not* as set forth in the Notes to § 73.3555 of this chapter, to the extent that there are any differences in such calculation methods.

(2) Each petitioning common carrier radio station applicant or licensee filing under § 1.5000(a)(2) shall identify and request specific approval for any foreign individual, entity, or group of such individuals or entities that holds, or would hold, directly, and/or indirectly through one or more intervening U.S.-organized entities that do not control the applicant or licensee, more than 5 percent of the equity and/or voting interests in the applicant or licensee unless the foreign investment is exempt under paragraph (i)(3) of this section. Equity and voting interests shall be calculated in accordance with the principles set forth in paragraphs (e) and (f) of this section and in § 1.5002.

Note 1 to paragraphs (i)(1) and (2): Certain foreign interests of 5 percent or less may require specific approval under paragraphs (i)(1) and (2). See the Note to paragraph (i)(3)(ii)(C) of this section.

Note 2 to paragraphs (i)(1) and (2): Two or more individuals or entities will be treated as a ''group'' when they have agreed to act together for the purpose of acquiring, holding, voting, or disposing of their equity and/or voting interests in the licensee and/or controlling U.S. parent of the licensee or in any intermediate company(ies) through which any of the individuals or entities holds its interests in the licensee and/or controlling U.S. parent of the licensee.

(3) A foreign investment is exempt from the specific approval requirements of paragraphs (i)(1) and (2) of this section where:

(i) The foreign individual or entity holds, or would hold, directly and/or indirectly, no more than 10 percent of the equity and/or voting interests of the U.S. parent (for petitions filed under § 1.5000(a)(1)) or the petitioning applicant or licensee (for petitions filed under § 1.5000(a)(2)); *and*

(ii) The foreign individual or entity does not hold, and would not hold, a controlling interest in the petitioner or any controlling parent company, does not plan or intend to change or influence control of the petitioner or any controlling parent company, does not possess or develop any such purpose, and does not take any action having such purpose or effect. The Commission will presume, in the absence of evidence to the contrary, that the following interests satisfy this criterion for exemption from the specific approval requirements in paragraphs (i)(1) and (2) of this section:

(A) Where the petitioning applicant or licensee, controlling U.S. parent, or entity holding a direct or indirect equity and/or voting interest in the applicant/licensee or U.S. parent is a ''public company,'' as defined in § 1.5000(d)(9), *provided that* the foreign holder is an institutional investor that is eligible to report its beneficial ownership interests in the company's voting, equity securities in excess of 5 percent (not to exceed 10 percent) pursuant to Exchange Act Rule 13d–1(b), 17 CFR 240.13d–1(b), or a substantially comparable foreign law or regulation. This presumption shall not apply if the foreign individual, entity or group holding such interests is obligated to report its holdings in the company pursuant to Exchange Act Rule 13d–1(a), 17 CFR 240.13d–1(a), or a substantially comparable foreign law or regulation.

Example. Common carrier applicant (''Applicant'') is preparing a petition for declaratory ruling to request Commission approval for foreign ownership of its controlling, U.S.-organized parent (''U.S. Parent'') to exceed the 25 percent benchmark in section 310(b)(4) of the Act. Applicant does not currently hold any FCC licenses. Shares of U.S. Parent trade publicly on the New York Stock Exchange. Based on a shareholder survey and a review of its shareholder records, U.S. Parent has determined that its aggregate foreign ownership on any given day may exceed an aggregate 25 percent, including a six percent common stock interest held by a foreign-organized mutual fund (''Foreign Fund''). U.S. Parent has confirmed that Foreign Fund is not currently required to report its interest pursuant to Exchange Act Rule 13d–1(a) and instead is eligible to report its interest pursuant to Exchange Act Rule 13d–1(b). U.S. Parent also has confirmed that Foreign Fund does not hold any other interests in U.S. Parent's equity securities, whether of a class of voting or non-voting securities. Applicant may, but is not required to, request specific approval of Foreign Fund's six percent interest in U.S. Parent.

Note to paragraph (i)(3)(ii)(A): Where an institutional investor holds voting, equity securities that are subject to reporting under Exchange Act Rule 13d–1, 17 CFR 240.13d–1, or a substantially comparable foreign law or regulation, in addition to equity securities that are not subject to such reporting, the investor's total capital stock interests may be aggregated and treated as exempt from the 5 percent specific approval requirement in paragraphs (i)(1) and (2) of this section so long as the aggregate amount of the institutional investor's holdings does not exceed ten percent of the company's total capital stock or voting rights and the investor is eligible to certify under Exchange Act Rule 13d–1(b), 17 CFR 240.13d–1(b), or a substantially comparable foreign law or regulation that it has acquired its capital stock interests in the ordinary course of business and not with the purpose nor with the effect of changing or influencing the control of the company. In calculating foreign equity and voting interests, the Commission does not consider convertible interests such as options, warrants and convertible debentures until converted, unless specifically requested by the petitioner, *i.e.,* where the petitioner is requesting approval so those rights can be exercised in a particular case without further Commission approval.

(B) Where the petitioning applicant or licensee, controlling U.S. parent, or entity holding a direct and/or indirect equity and/or voting interest in the applicant/licensee or U.S. parent is a ''privately held'' corporation, as defined in § 1.5000(d)(8), *provided that* a shareholders' agreement, or similar voting agreement, prohibits the foreign holder from becoming actively involved in the management or operation of the corporation and limits the foreign holder's voting and consent rights, if any, to the minority shareholder protections listed in paragraph (i)(5) of this section.

(C) Where the petitioning applicant or licensee, controlling U.S. parent, or entity holding a direct and/or indirect equity and/or voting interest in the licensee or U.S. parent is ''privately held,'' as defined in § 1.5000(d)(8), and is organized as a limited partnership, limited liability company (''LLC''), or limited liability partnership (''LLP''), *provided that* the foreign holder is ''insulated'' in accordance with the criteria specified in § 1.5003.

Note to paragraph (i)(3)(ii)(C): For purposes of identifying foreign interests that require specific approval, uninsulated partners, uninsulated LLC members, and non-member LLC managers are deemed to hold the same *voting* interest as the partnership or LLC holds in the company situated in the next lower tier of the petitioner's vertical ownership chain. *See* § 1.5002(b)(2)(ii)(A) and (b)(2)(iii)(A). Depending on the particular ownership structure presented in the petition, a foreign uninsulated partner, LLC member, or non-member LLC manager may be deemed to hold a direct or indirect *voting* interest in the controlling U.S. parent (for petitions filed under § 1.5000(a)(1)) or in the petitioning

applicant or licensee (for petitions filed under § 1.5000(a)(2)) that requires specific approval because the *voting* interest exceeds the 5 percent amount specified in paragraphs (i)(1) and (2) of this section and, because it is an uninsulated interest, the voting interest would not qualify as exempt from specific approval under this paragraph (i)(3)(ii)(C) even in circumstances where the voting interest does not exceed 10 percent.

(4) A petitioner may, but is not required to, request specific approval for any other foreign individual or entity that holds, or would hold, a direct and/or indirect equity and/or voting interest in the controlling U.S. parent (for petitions filed under § 1.5000(a)(1)) or in the petitioning applicant or licensee (for petitions filed under § 1.5000(a)(2)).

(5) The minority shareholder protections referenced in paragraph (i)(3)(ii)(B) of this section consist of the following rights:

(i) The power to prevent the sale or pledge of all or substantially all of the assets of the corporation or a voluntary filing for bankruptcy or liquidation;

(ii) The power to prevent the corporation from entering into contracts with majority shareholders or their affiliates;

(iii) The power to prevent the corporation from guaranteeing the obligations of majority shareholders or their affiliates;

(iv) The power to purchase an additional interest in the corporation to prevent the dilution of the shareholder's *pro rata* interest in the event that the corporation issues additional instruments conveying shares in the company;

(v) The power to prevent the change of existing legal rights or preferences of the shareholders, as provided in the charter, by-laws or other operative governance documents;

(vi) The power to prevent the amendment of the charter, by-laws or other operative governance documents of the company with respect to the matters described in paragraph (i)(5)(i) through (v) of this section.

(6) The Commission reserves the right to consider, on a case-by-case basis, whether voting or consent rights over matters other than those listed in paragraph (i)(5) of this section shall be considered permissible minority shareholder protections in a particular case.

(j) For each foreign individual or entity named in response to paragraph (i) of this section, provide the following information:

(1) In the case of an individual, his or her citizenship and principal business(es);

(2) In the case of a business organization:

(i) Its place of organization, type of business organization (*e.g.,* corporation, unincorporated association, trust, general partnership, limited partnership, limited liability company, trust, other (include description of legal entity)), and principal business(es);

(ii)(A) For common carrier, aeronautical en route, and aeronautical fixed radio station applicants and licensees, the name of any individual or entity that holds, or would hold, directly and/or indirectly, through one or more intervening entities, 10 percent or more of the equity interests and/or voting interests, or a controlling interest, in the foreign entity for which the petitioner requests specific approval. Specify for each such interest holder, his or her citizenship (for individuals) or place of legal organization (for entities). Equity interests and voting interests held indirectly shall be calculated in accordance with the principles set forth in § 1.5002.

(B) For broadcast applicants and licensees, the name of any individual or entity that holds, or would hold, directly and/or indirectly, through one or more intervening entities, an attributable interest in the foreign entity for which the petitioner requests specific approval. Specify for each such interest holder, his or her citizenship (for individuals) or place of legal organization (for entities). Attributable interests shall be calculated in accordance with the principles set forth in the Notes to § 73.3555 of this chapter.

(iii)(A) For common carrier, aeronautical en route, and aeronautical fixed radio station applicants and licensees, where no individual or entity holds, or would hold, directly and/or indirectly, 10 percent or more of the equity interests and/or voting interests, or a controlling interest, the petition shall specify that no individual or entity holds, or would hold, directly and/or indirectly, 10 percent or more of the equity interests and/or voting interests, or a controlling interest, in the foreign entity for which the petitioner requests specific approval.

(B) For broadcast applicants and licensees, where no individual or entity holds, or would hold, directly and/or indirectly, an attributable interest in the foreign entity, the petition shall specify that no individual or entity holds, or would hold, directly and/or indirectly, an attributable interest in the foreign entity for which the petitioner requests specific approval.

(k) *Requests for advance approval.* The petitioner may, but is not required to, request advance approval in its petition for any foreign individual or entity named in response to paragraph (i) of this section to increase its direct and/or indirect equity and/or voting interests in the controlling U.S. parent of the broadcast, common carrier or aeronautical radio station licensee, for petitions filed under § 1.5000(a)(1), and/or in the common carrier licensee, for petitions filed under § 1.5000(a)(2), above the percentages specified in response to paragraph (i) of this section. Requests for advance approval shall be made as follows:

(1) *Petitions filed under § 1.5000(a)(1).* Where a foreign individual or entity named in response to paragraph (i) of this section holds, or would hold upon consummation of any transactions described in the petition, a *de jure* or *de facto* controlling interest in the controlling U.S. parent, the petitioner may request advance approval in its petition for the foreign individual or entity to increase its interests, at some future time, up to any amount, including 100 percent of the direct and/or indirect equity and/or voting interests in the U.S. parent. The petitioner shall specify for the named controlling foreign individual(s) or entity(ies) the maximum percentages of equity and/or voting interests for which advance approval is sought or, in lieu of a specific amount, state that the petitioner requests advance approval for the named controlling foreign individual or entity to increase its interests up to and including 100 percent of the U.S. parent's direct and/or indirect equity and/or voting interests.

(2*) Petitions filed under § 1.5000(a)(1) and/or (2).* Where a foreign individual or entity named in response to paragraph (i) of this section holds, or would hold upon consummation of any transactions described in the petition, a non-controlling interest in the controlling U.S. parent of the licensee, for petitions filed under § 1.5000(a)(1), or in the licensee, for petitions filed under § 1.5000(a)(2), the petitioner may request advance approval in its petition for the foreign individual or entity to increase its interests, at some future time, up to any non-controlling amount not to exceed 49.99 percent. The petitioner shall specify for the named foreign individual(s) or entity(ies) the maximum percentages of equity and/or voting interests for which advance approval is sought or, in lieu of a specific amount, shall state that the petitioner requests advance approval for the named foreign individual(s) or entity(ies) to increase their interests up to and including a non-controlling 49.99 percent equity and/or voting interest in the licensee, for petitions filed under § 1.5000(a)(2), or in the controlling U.S.

parent of the licensee, for petitions filed under § 1.5000(a)(1).

(l) Each applicant, licensee, or spectrum lessee filing a petition for declaratory ruling shall certify to the information contained in the petition in accordance with the provisions of § 1.16 and the requirements of § 1.5000(c)(1).

§ 1.5002 How to calculate indirect equity and voting interests.

(a) The criteria specified in this section shall be used for purposes of calculating indirect equity and voting interests under § 1.5001.

(b)(1) *Equity interests held indirectly in the licensee and/or controlling U.S. parent.* Equity interests that are held by an individual or entity indirectly through one or more intervening entities shall be calculated by successive multiplication of the equity percentages for each link in the vertical ownership chain, regardless of whether any particular link in the chain represents a controlling interest in the company positioned in the next lower tier.

Example under § 1.5000(a)(1). Assume that a foreign individual holds a non-controlling 30 percent equity and voting interest in U.S.-organized Corporation A which, in turn, holds a non-controlling 40 percent equity and voting interest in U.S.-organized Parent Corporation B. The foreign individual's equity interest in U.S.-organized Parent Corporation B would be calculated by multiplying the foreign individual's equity interest in U.S.-organized Corporation A by that entity's equity interest in U.S.-organized Parent Corporation B. The foreign individual's equity interest in U.S.-organized Parent Corporation B would be calculated as 12 percent (30% × 40% = 12%). The result would be the same even if U.S.-organized Corporation A held a *de facto* controlling interest in U.S.-organized Parent Corporation B.

(2) *Voting interests held indirectly in the licensee and/or controlling U.S. parent.* Voting interests that are held by any individual or entity indirectly through one or more intervening entities will be determined depending upon the type of business organization(s) in which the individual or entity holds a voting interest as follows:

(i) Voting interests that are held through one or more intervening corporations shall be calculated by successive multiplication of the voting percentages for each link in the vertical ownership chain, except that wherever the voting interest for any link in the chain is equal to or exceeds 50 percent or represents actual control, it shall be treated as if it were a 100 percent interest.

Example under § 1.5000(a)(1). Assume that a foreign individual holds a non-controlling 30 percent equity and voting interest in U.S.-organized Corporation A which, in turn, holds a *controlling* 70 percent equity and voting interest in U.S.-organized Parent Corporation B. Because U.S.-organized Corporation A's 70 percent voting interest in U.S.-organized Parent Corporation B constitutes a *controlling* interest, it is treated as a 100 percent interest. The foreign individual's 30 percent voting interest in U.S.-organized Corporation A would flow through in its entirety to U.S. Parent Corporation B and thus be calculated as 30 percent (30% × 100% = 30%).

(ii) Voting interests that are held through one or more intervening partnerships shall be calculated depending upon whether the individual or entity holds a general partnership interest, an uninsulated partnership interest, or an insulated partnership interest as specified in paragraphs (b)(2)(ii)(A) and (B) of this section.

(A) *General partnership and other uninsulated partnership interests.* A general partner and uninsulated partner shall be deemed to hold the same voting interest as the partnership holds in the company situated in the next lower tier of the vertical ownership chain. A partner shall be treated as uninsulated unless the limited partnership agreement, limited liability partnership agreement, or other operative agreement satisfies the insulation criteria specified in § 1.5003.

(B) *Insulated partnership interests.* A partner of a limited partnership (other than a general partner) or partner of a limited liability partnership that satisfies the insulation criteria specified in § 1.5003 shall be treated as an insulated partner and shall be deemed to hold a voting interest in the partnership that is equal to the partner's equity interest.

Note to paragraph (b)(2)(ii): The Commission presumes that a general partner of a general partnership or limited partnership has a controlling interest in the partnership. A general partner shall in all cases be deemed to hold an uninsulated interest in the partnership.

(iii) Voting interests that are held through one or more intervening limited liability companies shall be calculated depending upon whether the individual or entity is a non-member manager, an uninsulated member or an insulated member as specified in paragraphs (b)(2)(iii)(A) and (B) of this section.

(A) *Non-member managers and uninsulated membership interests.* A non-member manager and an uninsulated member of a limited liability company shall be deemed to hold the same voting interest as the limited liability company holds in the company situated in the next lower tier of the vertical ownership chain. A member shall be treated as uninsulated unless the limited liability company agreement satisfies the insulation criteria specified in § 1.5003.

(B) *Insulated membership interests.* A member of a limited liability company that satisfies the insulation criteria specified in § 1.5003 shall be treated as an insulated member and shall be deemed to hold a voting interest in the limited liability company that is equal to the member's equity interest.

§ 1.5003 Insulation criteria for interests in limited partnerships, limited liability partnerships, and limited liability companies.

(a) A limited partner of a limited partnership and a partner of a limited liability partnership shall be treated as uninsulated within the meaning of § 1.5002(b)(2)(ii)(A) unless the partner is prohibited by the limited partnership agreement, limited liability partnership agreement, or other operative agreement from, and in fact is not engaged in, active involvement in the management or operation of the partnership and only the usual and customary investor protections are contained in the partnership agreement or other operative agreement. These criteria apply to any relevant limited partnership or limited liability partnership, whether it is the licensee, a controlling U.S.-organized parent, or any partnership situated above them in the vertical chain of ownership. Notwithstanding the foregoing, the insulation of limited partnership and limited liability partnership interests for broadcast applicants and licensees *shall* be determined in accordance with Note 2(f) of § 73.3555 of this chapter.

(b) A member of a limited liability company shall be treated as uninsulated for purposes of § 1.5002(b)(2)(iii)(A) unless the member is prohibited by the limited liability company agreement from, and in fact is not engaged in, active involvement in the management or operation of the company and only the usual and customary investor protections are contained in the agreement. These criteria apply to any relevant limited liability company, whether it is the licensee, a controlling U.S.-organized parent, or any limited liability company situated above them in the vertical chain of ownership. Notwithstanding the foregoing, the insulation of limited liability company interests for broadcast applicants and licensees *shall* be determined in accordance with Note 2(f) of § 73.3555 of this chapter.

(c) The usual and customary investor protections referred to in paragraphs (a) and (b) of this section shall consist of:

(1) The power to prevent the sale or pledge of all or substantially all of the assets of the limited partnership, limited liability partnership, or limited liability company or a voluntary filing for bankruptcy or liquidation;

(2) The power to prevent the limited partnership, limited liability partnership, or limited liability company from entering into contracts with majority investors or their affiliates;

(3) The power to prevent the limited partnership, limited liability partnership, or limited liability company from guaranteeing the obligations of majority investors or their affiliates;

(4) The power to purchase an additional interest in the limited partnership, limited liability partnership, or limited liability company to prevent the dilution of the partner's or member's *pro rata* interest in the event that the limited partnership, limited liability partnership, or limited liability company issues additional instruments conveying interests in the partnership or company;

(5) The power to prevent the change of existing legal rights or preferences of the partners, members, or managers as provided in the limited partnership agreement, limited liability partnership agreement, or limited liability company agreement, or other operative agreement;

(6) The power to vote on the removal of a general partner, managing partner, managing member, or other manager in situations where such individual or entity is subject to bankruptcy, insolvency, reorganization, or other proceedings relating to the relief of debtors; adjudicated insane or incompetent by a court of competent jurisdiction (in the case of a natural person); convicted of a felony; or otherwise removed for cause, as determined by an independent party;

(7) The power to prevent the amendment of the limited partnership agreement, limited liability partnership agreement, or limited liability company agreement, or other organizational documents of the partnership or limited liability company with respect to the matters described in paragraph (c)(1) through (c)(6) of this section.

(d) The Commission reserves the right to consider, on a case-by-case basis, whether voting or consent rights over matters other than those listed in paragraph (c) of this section shall be considered usual and customary investor protections in a particular case.

§ 1.5004 Routine terms and conditions.

Foreign ownership rulings issued pursuant to §§ 1.5000 through 1.5004 shall be subject to the following terms and conditions, except as otherwise specified in a particular ruling:

(a)(1) *Aggregate allowance for rulings issued under § 1.5000(a)(1).* In addition to the foreign ownership interests approved specifically in a licensee's declaratory ruling issued pursuant to § 1.5000(a)(1), the controlling U.S.-organized parent named in the ruling (or a U.S.-organized successor-in-interest formed as part of a *pro forma* reorganization) may be 100 percent owned, directly and/or indirectly through one or more U.S- or foreign-organized entities, on a going-forward basis (*i.e.,* after issuance of the ruling) by other foreign investors without prior Commission approval. This ''100 percent aggregate allowance'' is subject to the requirement that the licensee seek and obtain Commission approval before any foreign individual, entity, or ''group'' not previously approved acquires, directly and/or indirectly, more than five percent of the U.S. parent's outstanding capital stock (equity) and/or voting stock, or a controlling interest, with the exception of any foreign individual, entity, or ''group'' that acquires an equity and/or voting interest of ten percent or less, *provided that* the interest is exempt under § 1.5001(i)(3).

(2) *Aggregate allowance for rulings issued under § 1.5000(a)(2).* In addition to the foreign ownership interests approved specifically in a licensee's declaratory ruling issued pursuant to § 1.5000(a)(2), the licensee(s) named in the ruling (or a U.S.-organized successor-in-interest formed as part of a *pro forma* reorganization) may be 100 percent owned on a going forward basis (*i.e.,* after issuance of the ruling) by other foreign investors holding interests in the licensee indirectly through U.S.-organized entities that do not control the licensee, without prior Commission approval. This ''100 percent aggregate allowance'' is subject to the requirement that the licensee seek and obtain Commission approval before any foreign individual, entity, or ''group'' not previously approved acquires directly and/or indirectly, through one or more U.S.-organized entities that do not control the licensee, more than five percent of the licensee's outstanding capital stock (equity) and/or voting stock, with the exception of any foreign individual, entity, or ''group'' that acquires an equity and/or voting interest of ten percent or less, *provided that* the interest is exempt under § 1.5001(i)(3). Foreign ownership interests held directly in a licensee shall not be permitted to exceed an aggregate 20 percent of the licensee's equity and/or voting interests.

Note to paragraph (a): Licensees have an obligation to monitor and stay ahead of changes in foreign ownership of their controlling U.S.-organized parent companies (for rulings issued pursuant to § 1.5000(a)(1)) and/or in the licensee itself (for rulings issued pursuant to § 1.5000(a)(2)), to ensure that the licensee obtains Commission approval before a change in foreign ownership renders the licensee out of compliance with the terms and conditions of its declaratory ruling(s) or the Commission's rules. Licensees, their controlling parent companies, and other entities in the licensee's vertical ownership chain may need to place restrictions in their bylaws or other organizational documents to enable the licensee to ensure compliance with the terms and conditions of its declaratory ruling(s) and the Commission's rules.

Example 1 (for rulings issued under § 1.5000(a)(1)). U.S. Corp. files an application for a common carrier license. U.S. Corp. is wholly owned and controlled by U.S. Parent, which is a newly formed, privately held Delaware Corporation in which no single shareholder has *de jure* or *de facto* control. A shareholders' agreement provides that a five-member board of directors shall govern the affairs of the company; five named shareholders shall be entitled to one seat and one vote on the board; and all decisions of the board shall be determined by majority vote. The five named shareholders and their respective equity interests are as follows: Foreign Entity A, which is wholly owned and controlled by a foreign citizen (5 percent); Foreign Entity B, which is wholly owned and controlled by a foreign citizen (10 percent); Foreign Entity C, a foreign public company with no controlling shareholder (20 percent); Foreign Entity D, a foreign pension fund that is controlled by a foreign citizen and in which no individual or entity has a pecuniary interest exceeding one percent (21 percent); and U.S. Entity E, a U.S. public company with no controlling shareholder (25 percent). The remaining 19 percent of U.S. Parent's shares are held by three foreign-organized entities as follows: F (4 percent), G (6 percent), and H (9 percent). Under the shareholders' agreement, voting rights of F, G, and H are limited to the minority shareholder protections listed in § 1.5001(i)(5). Further, the agreement expressly prohibits G and H from becoming actively involved in the management or operation of U.S. Parent and U.S. Corp.

As required by the rules, U.S. Corp. files a section 310(b)(4) petition concurrently with its application. The petition identifies and requests specific approval for the ownership interests held in U.S. Parent by Foreign Entity A and its sole shareholder (5 percent equity and 20 percent voting interest); Foreign Entity B and its sole shareholder (10 percent equity and 20 percent voting interest), Foreign Entity C (20 percent equity and 20 percent voting interest), and Foreign Entity D (21 percent equity and 20 percent

voting interest) and its fund manager (20 percent voting interest). The Commission's ruling specifically approves these foreign interests. The ruling also provides that, on a going-forward basis, U.S. Parent may be 100 percent owned in the aggregate, directly and/or indirectly, by other foreign investors, subject to the requirement that U.S. Corp. seek and obtain Commission approval before any previously unapproved foreign investor acquires more than five percent of U.S. Parent's equity and/or voting interests, or a controlling interest, with the exception of any foreign investor that acquires an equity and/or voting interest of ten percent or less, *provided that* the interest is exempt under § 1.991(i)(3).

In this case, foreign entities F, G, and H would each be considered a previously unapproved foreign investor (along with any new foreign investors). However, prior approval for F, G and H would only apply to an increase of F's interest above five percent (because the ten percent exemption under § 1.5001(i)(3) does not apply to F) or to an increase of G's or H's interest above ten percent (because G and H do qualify for this exemption). U.S. Corp. would also need Commission approval before Foreign Entity D appoints a new fund manager that is a non-U.S. citizen and before Foreign Entities A, B, C, or D increase their respective equity and/or voting interests in U.S. Parent, unless the petition previously sought and obtained Commission approval for such increases (up to non-controlling 49.99 percent interests). (*See* § 1.5001(k)(2).) Foreign shareholders of Foreign Entity C and U.S. Entity E would also be considered previously unapproved foreign investors. Thus, Commission approval would be required before any foreign shareholder of Foreign Entity C or U.S. Entity E acquires (1) a controlling interest in either company; or (2) a non-controlling equity and/or voting interest in either company that, when multiplied by the company's equity and/or voting interests in U.S. Parent, would exceed 5 percent of U.S. Parent's equity and/or voting interests, unless the interest is exempt under § 1.5001(i)(3).

Example 2 (for rulings issued under § 1.5000(a)(2)). Assume that the following three U.S.-organized entities hold non-controlling equity and voting interests in common carrier Licensee, which is a privately held corporation organized in Delaware: U.S. corporation A (30 percent); U.S. corporation B (30 percent); and U.S. corporation C (40 percent). Licensee's shareholders are wholly owned by foreign individuals X, Y, and Z, respectively. Licensee has received a declaratory ruling under § 1.5000(a)(2) specifically approving the 30 percent foreign ownership interests held in Licensee by each of X and Y (through U.S. corporation A and U.S. corporation B, respectively) and the 40 percent foreign ownership interest held in Licensee by Z (through U.S. corporation C). On a going-forward basis, Licensee may be 100 percent owned in the aggregate by X, Y, Z, and other foreign investors holding interests in Licensee indirectly, through U.S.-organized entities that do not control Licensee, subject to the requirement that Licensee obtain Commission approval before any previously unapproved foreign investor acquires more than five percent of Licensee's equity and/or voting interests, with the exception of any foreign investor that acquires an equity and/or voting interest of ten percent or less, *provided that* the interest is exempt under § 1.5001(i)(3). In this case, any foreign investor other than X, Y, and Z would be considered a previously unapproved foreign investor. Licensee would also need Commission approval before X, Y, or Z increases its equity and/or voting interests in Licensee unless the petition previously sought and obtained Commission approval for such increases (up to non-controlling 49.99 percent interests). (*See* § 1.5001(k)(2).)

(b) *Subsidiaries and affiliates.* A foreign ownership ruling issued to a licensee shall cover it *and* any U.S.-organized subsidiary or affiliate, as defined in § 1.5000(d), whether the subsidiary or affiliate existed at the time the ruling was issued or was formed or acquired subsequently, *provided that* the foreign ownership of the licensee named in the ruling, and of the subsidiary and/or affiliate, remains in compliance with the terms and conditions of the licensee's ruling and the Commission's rules.

(1) The subsidiary or affiliate of a licensee named in a foreign ownership ruling issued under § 1.5000(a)(1) may rely on that ruling for purposes of filing its own application for an initial broadcast, common carrier or aeronautical license or spectrum leasing arrangement, or an application to acquire such license or spectrum leasing arrangement by assignment or transfer of control *provided that* the subsidiary or affiliate, and the licensee named in the ruling, each certifies in the application that its foreign ownership is in compliance with the terms and conditions of the foreign ownership ruling and the Commission's rules.

(2) The subsidiary or affiliate of a licensee named in a foreign ownership ruling issued under § 1.5000(a)(2) may rely on that ruling for purposes of filing its own application for an initial common carrier radio station license or spectrum leasing arrangement, or an application to acquire such license or spectrum leasing arrangement by assignment or transfer of control *provided that* the subsidiary or affiliate, and the licensee named in the ruling, each certifies in the application that its foreign ownership is in compliance with the terms and conditions of the foreign ownership ruling and the Commission's rules.

(3) The certifications required by paragraphs (b)(1) and (b)(2) of this section shall also include the citation(s) of the relevant ruling(s) (*i.e.,* the DA or FCC Number, FCC Record citation when available, and release date).

(c) *Insertion of new controlling foreign-organized companies.* (1) Where a licensee's foreign ownership ruling specifically authorizes a named, foreign investor to hold a controlling interest in the licensee's controlling U.S.-organized parent, for rulings issued under § 1.5000(a)(1), or in an intervening U.S.-organized entity that does not control the licensee, for rulings issued under § 1.5000(a)(2), the ruling shall permit the insertion of new, controlling foreign-organized companies in the vertical ownership chain above the controlling U.S. parent, for rulings issued under § 1.5000(a)(1), or above an intervening U.S.-organized entity that does not control the licensee, for rulings issued under § 1.5000(a)(2), without prior Commission approval *provided that* any new foreign-organized company(ies) are under 100 percent common ownership and control with the foreign investor approved in the ruling.

(2) Where a previously unapproved foreign-organized entity is inserted into the vertical ownership chain of a licensee, or its controlling U.S.-organized parent, without prior Commission approval pursuant to paragraph (c)(1) of this section, the licensee shall file a letter to the attention of the Chief, International Bureau, within 30 days after the insertion of the new, foreign-organized entity. The letter must include the name of the new, foreign-organized entity and a certification by the licensee that the entity complies with the 100 percent common ownership and control requirement in paragraph (c)(1) of this section. The letter must also reference the licensee's foreign ownership ruling(s) by IBFS File No. and FCC Record citation, if available. This letter notification need not be filed if the ownership change is instead the subject of a *pro forma* application or *pro forma* notification already filed with the Commission pursuant to the relevant broadcast service rules, wireless radio service rules or satellite radio service rules applicable to the licensee.

Note to paragraph (c)(2): For broadcast stations, in order to insert a previously unapproved foreign-organized entity that is under 100 percent common ownership and control with the foreign investor approved in the ruling into the vertical ownership chain of the licensee's controlling U.S.-organized parent, as described in paragraph (c)(1) of this section, the licensee must always file a *pro forma* application requesting prior consent of the FCC pursuant to section 73.3540(f) of this chapter.

(3) Nothing in this section is intended to affect any requirements for prior approval under 47 U.S.C. 310(d) or conditions for forbearance from the

requirements of 47 U.S.C. 310(d) pursuant to 47 U.S.C. 160.

Example (for rulings issued under § 1.5000(a)(1)). Licensee of a common carrier license receives a foreign ownership ruling under § 1.5000(a)(1) that authorizes its controlling, U.S.-organized parent (''U.S. Parent A'') to be wholly owned and controlled by a foreign-organized company (''Foreign Company''). Foreign Company is minority owned (20 percent) by U.S.-organized Corporation B, with the remaining 80 percent controlling interest held by Foreign Citizen C. After issuance of the ruling, Foreign Company forms a wholly-owned, foreign-organized subsidiary (''Foreign Subsidiary'') to hold all of Foreign Company's shares in U.S. Parent A. There are no other changes in the direct or indirect foreign ownership of U.S. Parent A. The insertion of Foreign Subsidiary into the vertical ownership chain between Foreign Company and U.S. Parent A would not require prior Commission approval, except for any approval otherwise required pursuant to section 310(d) of the Communication+s Act and not exempt therefrom as a *pro forma* transfer of control under § 1.948(c)(1).

Example (for rulings issued under § 1.5000(a)(2)). An applicant for a common carrier license receives a foreign ownership ruling under § 1.5000(a)(2) that authorizes a foreign-organized company (''Foreign Company'') to hold a non-controlling 44 percent equity and voting interest in the applicant through Foreign Company's wholly-owned, U.S.-organized subsidiary, U.S. Corporation A, which holds the non-controlling 44 percent interest directly in the applicant. The remaining 56 percent of the applicant's equity and voting interests are held by its controlling U.S.-organized parent, which has no foreign ownership. After issuance of the ruling, Foreign Company forms a wholly-owned, foreign-organized subsidiary to hold all of Foreign Company's shares in U.S. Corporation A. There are no other changes in the direct or indirect foreign ownership of U.S. Corporation A. The insertion of the foreign-organized subsidiary into the vertical ownership chain between Foreign Company and U.S. Corporation A would not require prior Commission approval.

(d) *Insertion of new non-controlling foreign-organized companies.* (1) Where a licensee's foreign ownership ruling specifically authorizes a named, foreign investor to hold a non-controlling interest in the licensee's controlling U.S.-organized parent, for rulings issued under § 1.5000(a)(1), or in an intervening U.S.-organized entity that does not control the licensee, for rulings issued under § 1.5000(a)(2), the ruling shall permit the insertion of new, foreign-organized companies in the vertical ownership chain above the controlling U.S. parent, for rulings issued under § 1.5000(a)(1), or above an intervening U.S.-organized entity that does not control the licensee, for rulings issued under § 1.5000(a)(2), without prior Commission approval *provided that* any new foreign-organized company(ies) are under 100 percent common ownership and control with the foreign investor approved in the ruling.

Note to paragraph (d)(1): Where a licensee has received a foreign ownership ruling under § 1.5000(a)(2) and the ruling specifically authorizes a named, foreign investor to hold a non-controlling interest directly in the licensee (subject to the 20 percent aggregate limit on direct foreign investment), the ruling shall permit the insertion of new, foreign-organized companies in the vertical ownership chain of the approved foreign investor without prior Commission approval *provided that* any new foreign-organized companies are under 100 percent common ownership and control with the approved foreign investor.

Example (for rulings issued under § 1.5000(a)(1)). Licensee receives a foreign ownership ruling under § 1.5000(a)(1) that authorizes a foreign-organized company (''Foreign Company'') to hold a non-controlling 30 percent equity and voting interest in Licensee's controlling, U.S.-organized parent (''U.S. Parent A''). The remaining 70 percent equity and voting interests in U.S. Parent A are held by U.S.-organized entities which have no foreign ownership. After issuance of the ruling, Foreign Company forms a wholly-owned, foreign-organized subsidiary (''Foreign Subsidiary'') to hold all of Foreign Company's shares in U.S. Parent A. There are no other changes in the direct or indirect foreign ownership of U.S. Parent A. The insertion of Foreign Subsidiary into the vertical ownership chain between Foreign Company and U.S. Parent A would not require prior Commission approval.

Example (for rulings issued under § 1.5000(a)(2)). Licensee receives a foreign ownership ruling under § 1.5000(a)(2) that authorizes a foreign-organized entity (''Foreign Company'') to hold approximately 24 percent of Licensee's equity and voting interests, through Foreign Company's non-controlling 48 percent equity and voting interest in a U.S.-organized entity, U.S. Corporation A, which holds a non-controlling 49 percent equity and voting interest directly in Licensee. (A U.S. citizen holds the remaining 52 percent equity and voting interests in U.S. Corporation A, and the remaining 51 percent equity and voting interests in Licensee are held by its U.S.-organized parent, which has no foreign ownership. After issuance of the ruling, Foreign Company forms a wholly-owned, foreign-organized subsidiary (''Foreign Subsidiary'') to hold all of Foreign Company's shares in U.S. Corporation A. There are no other changes in the direct or indirect foreign ownership of U.S. Corporation A. The insertion of Foreign Subsidiary into the vertical ownership chain between Foreign Company and U.S. Corporation A would not require prior Commission approval.

(2) Where a previously unapproved foreign-organized entity is inserted into the vertical ownership chain of a licensee, or its controlling U.S.-organized parent, without prior Commission approval pursuant to paragraph (d)(1) of this section, the licensee shall file a letter to the attention of the Chief, International Bureau, within 30 days after the insertion of the new, foreign-organized entity; or in the case of a broadcast licensee, the licensee shall file a letter to the attention of the Chief, Media Bureau, within 30 days after the insertion of the new, foreign-organized entity. The letter must include the name of the new, foreign-organized entity and a certification by the licensee that the entity complies with the 100 percent common ownership and control requirement in paragraph (d)(1) of this section. The letter must also reference the licensee's foreign ownership ruling(s) by IBFS File No. and FCC Record citation, if available; or, if a broadcast licensee, the letter must reference the licensee's foreign ownership ruling(s) by CDBS File No., Docket No., call sign(s), facility identification number(s), and FCC Record citation, if available. This letter notification need not be filed if the ownership change is instead the subject of a *pro forma* application or *pro forma* notification already filed with the Commission pursuant to the relevant broadcast service, wireless radio service rules or satellite radio service rules applicable to the licensee.

(e) *New petition for declaratory ruling required.* A licensee that has received a foreign ownership ruling, including a U.S.-organized successor-in-interest to such licensee formed as part of a *pro forma* reorganization, or any subsidiary or affiliate relying on such licensee's ruling pursuant to paragraph (b) of this section, shall file a new petition for declaratory ruling under § 1.5000 to obtain Commission approval *before* its foreign ownership exceeds the routine terms and conditions of this section, and/or any specific terms or conditions of its ruling.

(f) *Continuing compliance.* (1) If at any time the licensee, including any successor-in-interest and any subsidiary or affiliate as described in paragraph (b) of this section, knows, or has reason to know, that it is no longer in compliance with its foreign ownership ruling or the Commission's rules relating to foreign ownership, it shall file a statement with the Commission explaining the circumstances within 30 days of the date it knew, or had reason to know, that it was no longer in compliance therewith. Subsequent actions taken by or on behalf of the licensee to remedy its non-compliance shall not relieve it of

the obligation to notify the Commission of the circumstances (including duration) of non-compliance. Such licensee and any controlling companies, whether U.S.- or foreign-organized, shall be subject to enforcement action by the Commission for such non-compliance, including an order requiring divestiture of the investor's direct and/or indirect interests in such entities.

(2) Any individual or entity that, directly or indirectly, creates or uses a trust, proxy, power of attorney, or any other contract, arrangement, or device with the purpose or effect of divesting itself, or preventing the vesting, of an equity interest or voting interest in the licensee, or in a controlling U.S. parent company, as part of a plan or scheme to evade the application of the Commission's rules or policies under section 310(b) shall be subject to enforcement action by the Commission, including an order requiring divestiture of the investor's direct and/or indirect interests in such entities.

PART 25—SATELLITE COMMUNICATIONS

■ 5. The authority citation for part 25 is revised to read as follows:

Authority: Interprets or applies Sections 4, 301, 302, 303, 307, 309, 310, 319, 332, 705, and 721 of the Communications Act, as amended, 47 U.S.C. Sections 154, 301, 302, 303, 307, 309, 310, 319, 332, 705, and 721 unless otherwise noted.

■ 6. Section 25.105 is revised to read as follows:

§ 25.105 Citizenship.

The rules that establish the requirements and conditions for obtaining the Commission's prior approval of foreign ownership in common carrier licensees that would exceed the 20 percent limit in section 310(b)(3) of the Communications Act (47 U.S.C. 310(b)(3)) and/or the 25 percent benchmark in section 310(b)(4) of the Act (47 U.S.C. 310(b)(4)) are set forth in §§ 1.5000 through 1.5004 of this chapter.

PART 73—RADIO BROADCAST SERVICES

■ 7. The authority citation for part 73 is revised to read as follows:

Authority: 47 U.S.C. 154, 303, 309, 310, 334, 336, and 339.

■ 8. Section 73.1010 is amended by revising paragraph (a)(9) and adding paragraph (a)(10) to read as follows:

§ 73.1010 Cross reference to rules in other parts.

* * * * *

(a) * * *

(9) Subpart T, ''Foreign Ownership of Broadcast, Common Carrier, Aeronautical En Route, and Aeronautical Fixed Radio Station Licensees''. (§§ 1.5000 to 1.5004).

(10) Part 1, Subpart W of this chapter, ''FCC Registration Number''. (§§ 1.8001–1.8005).

* * * * *

PART 74—EXPERIMENTAL RADIO, AUXILIARY, SPECIAL BROADCAST AND OTHER PROGRAM DISTRIBUTIONAL SERVICES

■ 9. The authority citation for part 74 is revised to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, 307, 309, 310, 336 and 554.

■ 10. Section 74.5 is amend by revising paragraph (a)(8) and adding paragraph (a)(9) to read as follows:

§ 74.5 Cross reference to rules in other parts.

* * * * *

(a) * * *

(8) Subpart T, ''Foreign Ownership of Broadcast, Common Carrier, Aeronautical En Route, and Aeronautical Fixed Radio Station Licensees''. (§§ 1.5000 to 1.5004).

(9) Part 1, Subpart W of the chapter, ''FCC Registration Number''. (§§ 1.8001–1.8005).

* * * * *

[FR Doc. 2015–28344 Filed 11–5–15; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 80, No. 215
Friday, November 6, 2015

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Medicine Bow-Routt Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Medicine Bow-Routt Resource Advisory Committee (RAC) will meet in Walden, Colorado. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://www.fs.usda.gov/goto/mbr/advisorycommittees*.

DATES: The meeting will be held on November 20, 2015, at 10:00 a.m., Mountain Standard Time.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under *For Further Information Contact.*

ADDRESSES: The meeting will be held at the Parks Ranger District Office, 100 Main Street, Walden, Colorado.

Written comments may be submitted as described under *Supplementary Information.* All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Medicine Bow-Routt National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Aaron Voos, RAC Coordinator, by phone at 307–745–2323 or via email at *atvoos@fs.fed.us*.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Review and recommend projects authorized under Title II of the Act, and
2. Update RAC members on the progress of previously approved projects.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by November 16, 2015, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Dennis Jaeger, RAC Designated Federal Officer, Medicine Bow-Routt National Forest Supervisor's Office, 2468 Jackson Street, Laramie, Wyoming 82070; by email to *djaeger01@fs.fed.us,* or via facsimile to 307–745–2467.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: November 2, 2015.

Dennis Jaeger,

Forest Supervisor, Medicine Bow-Routt National Forests & Thunder Basin National Grassland.

[FR Doc. 2015–28317 Filed 11–5–15; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Montana Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the Montana Advisory Committee to the Commission will convene at 1:00 p.m. (MDT) on Tuesday, November 17, 2015, via teleconference. The purpose of the planning meeting is for the Advisory Committee to continue their discussion and plans to conduct a community forum on Border Town Discrimination against Native Americans. Planning will include identifying specific issues to be addressed, presenters to be invited, and setting of the agenda.

Members of the public may listen to the discussion by dialing the following Conference Call Toll-Free Number: 1–888–329–8862; Conference ID: 3946131. Please be advised that before being placed into the conference call, the operator will ask callers to provide their names, their organizational affiliations (if any), and an email address (if available) prior to placing callers into the conference room. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free phone number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service (FRS) at 1–800–977–8339 and provide the FRS operator with the Conference Call Toll-Free Number: 1–888–329–8862, Conference ID: 3946131. Members of the public are invited to submit written comments; the comments must be received in the regional office by Thursday, December 17, 2015. Written comments may be mailed to the Rocky Mountain Regional Office, U.S. Commission on Civil Rights, 1961 Stout Street, Suite 13–201, Denver, CO 80294, faxed to (303) 866–1050, or emailed to Evelyn Bohor at *ebohor@usccr.gov.* Persons who desire additional information may contact the Rocky Mountain Regional Office at (303) 866–1040.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=259* and clicking on the ''Meeting Details'' and ''Documents''

links. Records generated from this meeting may also be inspected and reproduced at the Rocky Mountain Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov,* or to contact the Rocky Mountain Regional Office at the above phone number, email or street address.

Agenda:

Welcome and Introductions
Norma Bixby, Chair
Discussion of Specific Issues to Consider, Presenters and Setting the Briefing Agenda
Montana State Advisory Committee
Administrative Matters
Malee V. Craft, Regional Director and Designated Federal Official (DFO)

DATES: Tuesday, November 17, 2015, at 1:00 p.m. (MDT).

ADDRESSES: To be held via teleconference:

Conference Call Toll-Free Number: 1–888–329–8862, Conference ID: 3946131.

TDD: Dial Federal Relay Service 1–800–977–8339 and give the operator the above conference call number and conference ID.

FOR FURTHER INFORMATION CONTACT: Malee V. Craft, Regional Director, *mcraft@usccr.gov,* 303–866–1040.

Dated: November 2, 2015.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2015–28296 Filed 11–5–15; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of National Advisory Council on Innovation and Entrepreneurship Meeting

AGENCY: Economic Development Administration.

ACTION: Notice of an open meeting.

SUMMARY: The National Advisory Council on Innovation and Entrepreneurship (NACIE) will hold a public meeting on Thursday, December 3, 2015, 2:00–3:30 p.m. Eastern Time (ET) and Friday, December 4, 2015, 8:45 a.m.–12:00 p.m. ET. During this time, members will continue to work on various Council initiatives which include: innovation, entrepreneurship and workforce talent.

DATES:

Thursday, December 3, 2015
Time: 2:00–3:30 p.m. ET
Friday, December 4, 2015
Time: 8:45 a.m.–12:00 p.m. ET

ADDRESSES: Google, Inc., 25 Massachusetts Ave NW., #900, Washington, DC 20001.

Teleconference:
December 3–4, 2015
Dial-In: 1–800–369–1986
Passcode: 3758910

SUPPLEMENTARY INFORMATION: The Council was chartered on November 10, 2009 to advise the Secretary of Commerce on matters related to innovation and entrepreneurship in the United States. NACIE's overarching focus is recommending transformational policies to the Secretary that will help U.S. communities, businesses, and the workforce become more globally competitive. The Council operates as an independent entity within the Office of Innovation and Entrepreneurship (OIE), which is housed within the U.S. Commerce Department's Economic Development Administration. NACIE members are a diverse and dynamic group of successful entrepreneurs, innovators, and investors, as well as leaders from nonprofit organizations and academia.

The purpose of this meeting is to discuss the Council's planned work initiatives in three focus areas: Workforce/talent, entrepreneurship, and innovation. The final agenda will be posted on the NACIE Web site at *http://www.eda.gov/oie/nacie/* prior to the meeting. Any member of the public may submit pertinent questions and comments concerning the Council's affairs at any time before or after the meeting. Comments may be submitted to the Office of Innovation and Entrepreneurship at the contact information below. Those unable to attend the meetings in person but wishing to listen to the proceedings can do so through a conference call line: 1–800–369–1986, passcode: 3758910 for both meeting days on December 3rd and December 4th. Copies of the meeting minutes will be available by request within 90 days of the meeting date.

FOR FURTHER INFORMATION CONTACT: Julie Lenzer, Director, Office of Innovation and Entrepreneurship, Room 78018, 1401 Constitution Avenue NW., Washington, DC 20230; email: *NACIE@doc.gov;* telephone: 202–482–8001; fax: 202–273–4781. Please reference ''NACIE December 3rd–4th Meeting'' in the subject line of your correspondence.

Dated: November 2, 2015.

Julie Lenzer,

Director, Office of Innovation and Entrepreneurship.

[FR Doc. 2015–28320 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Department of Commerce.

ACTION: Notice and opportunity for public comment.

Pursuant to Section 251 of the Trade Act 1974, as amended (19 U.S.C. 2341 *et seq.*), the Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of these firms contributed importantly to the total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[10/7/2015 through 10/22/2015 (amended)]

Firm name	Firm address	Date accepted for investigation	Product(s)
Bliley Technologies, Inc	2545 West Grandview Boulevard, Erie, PA 16506.	10/14/2015	The firm manufactures custom quartz crystals and crystal oscillators.
Bonamar Corporation	7990 NW 53rd Street, Suite 336, Doral, FL 33166.	10/22/2015	The firm manufactures crabmeat using a process that consists of pasteurizing/cooking and packing the crabmeat.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE—Continued

[10/7/2015 through 10/22/2015 (amended)]

Firm name	Firm address	Date accepted for investigation	Product(s)
Hastings Irrigation Pipe Co	1801 East South Street, Hastings, ND 68901.	10/22/2015	The firm manufactures alumimun pipe.
Automation Systems, LLC	2001 N. 17th Avenue, Melrose Park, IL 60160.	10/22/2015	The firm manufactures bolt, screw, and washer assembled components for the automotive and commercial markets.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance for Firms Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Dated: November 2, 2015.

Miriam Kearse,

Lead Program Analyst.

[FR Doc. 2015–28321 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–70–2015]

Foreign-Trade Zone (FTZ) 39—Dallas/Fort Worth, Texas; Notification of Proposed Production Activity, KONE, Inc. (Elevator Parts), Allen, Texas

KONE, Inc. (KONE) submitted a notification of proposed production activity to the FTZ Board for its facility in Allen, Texas. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on October 29, 2015.

The KONE facility is located within Site 21 of FTZ 39. The facility is used for the research, testing and manufacturing of elevator logic control enclosure electrification panels and pick-and-pack elevator part kits. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt KONE from customs duty payments on the foreign status components used in export production. On its domestic sales, KONE would be able to choose the duty rates during customs entry procedures that apply to elevator logic control enclosure electrification panels and pick-and-pack elevator part kits (duty rate ranges from duty-free to 2.7%) for the foreign status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign status production equipment.

The components and materials sourced from abroad include: Adhesives; plastic rods; plastic tubes; plastic bushings; self-adhesive plastic electrical tape; plastic bumper strips in rolls; plastic guides and covers; plastic cover seals; plastic gaskets; plastic insulation; rubber gaskets; rubber pads; rubber isolation parts; paper film displays; paper labels; paper drilling templates; printed product information; galvanized steel sheets; galvanized steel wire; stainless steel sheets; steel profile parts; steel sheet piling; steel tubes; threaded steel elbows; threaded steel fittings; steel pipe fittings; steel chains; steel anchors; steel screws, bolts and nuts; steel spacer studs; steel lock washers; steel washers; steel rivets; steel cotter pins; steel mesh; steel rods; steel brackets; steel cabinets; copper plates; copper screws; copper nuts; copper springs; aluminum spacers; metal cabinet locks; lock parts (latch cam); base metal hinges for metal cabinets; base metal brackets, covers and handles for metal cabinets; base metal conduits and plates; sensors meant for weighing; circuit board parts; gearless motor stub shafts; bushings; roller screws; shaft couplings; clutches; electric motors; electric motor parts; electrical transformers; static converters; power inducers; electrical transformer parts; magnets; electromagnetic braking units; emergency intercoms; adapter modules; intercom/telephone parts; speakers; computerized voice recorders; printed circuit parts; pilot alarms; light indicator panels; pilot lights for printed circuits; resistor assemblies; resistor parts; fuses; automatic circuit breakers; resistor capacitor unit protectors; relay units; circuit breakers; electronic seismic switches; switches; electrical connectors; electrical couplings; main controller CPU with printed circuit boards; electrical boards; box back panels; electronic integrated circuit parts; electrical encoders; electric conductors; LED display counters; and, LED speed-direction indicators (duty rate ranges from duty-free to 12.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is December 16, 2015.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: October 30, 2015.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2015–28341 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–851]

Certain Preserved Mushrooms From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, and Rescission in Part; 2014/2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* November 6, 2015.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on certain preserved mushrooms from the People's Republic of China (PRC) covering the period February 1, 2014, through January 31, 2015. We preliminarily determine that the only respondent selected for individual examination in this review, Linyi City Kangfa Foodstuff Drinkable Co., Ltd. (Kangfa), is not eligible for a separate rate and, therefore, is considered part of the PRC-wide entity.[1] We invite interested parties to comment on these preliminary results.

FOR FURTHER INFORMATION CONTACT: Michael J. Heaney, or Robert James, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4475 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The products covered by this order are certain preserved mushrooms. The merchandise subject to this order is classifiable under subheadings: 2003.10.0127, 2003.10.0131, 2003.10.0137, 2003.10.0143, 2003.10.0147, 2003.10.0153, and 0711.51.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and Customs purposes, the written description of the scope of this order is dispositive.[2]

Background

On April 3, 2015, the Department published in the **Federal Register**, a notice of initiation of the antidumping duty administrative review of mushrooms from the PRC for the period February 1, 2014, through January 31, 2015, with respect to the 63 companies named in the review requests submitted by interested parties.[3] On April 29, 2015, the Department released to all interested parties having an administrative protective order (APO) CBP data for entries of the subject merchandise during the POR. We invited interested parties to comment regarding the CBP data and respondent selection. The Department received no comments concerning these CBP data. Moreover, based on our review of the CBP data, the Department determined that only Kangfa had reviewable entries. Accordingly, on June 11, 2015, the Department issued a questionnaire to Kangfa.

No Shipments Certifications

On May 1, 2015, (1) Dezhou Kaihang Agricultural Science Technology Co., Ltd., (Dezhou Kaihang), (2) Fujian Haishan Foods Co., Ltd. (Fujian Haishan), (3) Inter-Foods (Dongshan) Co., Ltd. (Inter-Foods), (4) Shandong Fengyu Edible Fungus Corporation Ltd. (Fengyu), (5) Xiamen International Trade & Industrial Co., Ltd. (XITIC), (6) Zhangzhou Gangchang Canned Foods Co., Ltd. (Gangchang) and (7) Zhangzhou Hongda Import & Export Trading Co., Ltd. (Hongda) submitted no shipment certifications.[4] On June 3, 2015, Guangxi Jisheng Foods, Inc. (Guangxi Jisheng) did so as well. On August 20, 2015, the Department sent inquiries to U.S. Customs and Border Protection (CBP) to confirm the no shipments certifications received from the following companies: (1) The exporter/producer combination of Dezhou Kaihang/Fengyu; (2) the exporter/producer combination of Fujian Haishan/Hongda; (3) XITIC; and (4) Gangchang.[5] On October 22, 2015, the Department sent an additional inquiry to CBP regarding the certification provided by Guangxi Jisheng.[6] To date, the Department has received no information contrary to the no shipment claims submitted.

Based on the no-shipment certifications and our analysis of the CBP information, we preliminarily determine that Dezhou Kaihang/Fengyu, Fujian Haishan/Hongda, XITIC, Gangchang, and Guangxi Jisheng did not have any reviewable transactions during the POR. In addition, for Dezhou Kaihang/Fengyu, Fujian Haishan/Hongda, XITIC, Gangchang, and Guangxi Jisheng, the Department finds that consistent with its refinement to its assessment practice in non-market economy (NME) cases, it is appropriate not to rescind the review in part in this circumstance but, rather, to complete the review with respect to these companies and issue appropriate instructions to CBP based on the final results of the review.[7] If the Department continues to determine in the final results of this review that these companies have no reviewable transactions, we intend to instruct CBP to continue to collect cash deposits of estimated antidumping duties at the current rate in effect for those companies.[8]

Partial Rescission

Section 351.213(d)(1) of the Department's regulations provides that the Department will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request for review within 90 days of the date of publication of the notice of initiation of the requested review. The Department published the *Initiation Notice* on April 3, 2015.[9]

On July 2, 2015, Monterey Mushrooms withdrew its request for review of 27 companies, including (1)Fujian Tongfa Foods Group Co., Ltd. (Fujian Tongfa), (2) Mikado Food China Co., Ltd. (Mikado), (3) Xiamen Hua Min Import & Export Co., Ltd., (4) Zhangzhou Tan Co. Ltd., Fujian, China and (5) Zhangzhou Yuxing Import & Export Trading Co., Ltd. No other party has requested a review of any of the five companies indicated above. Because all review requests have been timely withdrawn, we are rescinding this review with respect to these companies. For the remaining 22 companies, there continue to be active review requests; therefore, we are not rescinding the review for those companies.

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[1] *See* Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Certain Preserved Mushrooms from the People's Republic of China; 2014–2015 from Christian Marsh Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, dated November 2, 2015 (Preliminary Decision Memorandum), issued concurrently with and hereby adopted by this notice.

[2] See Preliminary Decision Memorandum for a complete description of the Scope of the Order.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews, Request for Revocation in Part,* 80 FR 18202, 18207–08 (April 3, 2015) (*Initiation Notice*).

[4] The Department assigned separate ''combination'' rates to 1) Dezhou Kaihang/Fengyu and 2) Fujian Haishan/Hongda as the result of new shipper reviews. *See Certain Preserved Mushrooms From the People's Republic of China: Final Results of Antidumping Duty New Shipper Review* 80 FR 32352, (June 8, 2015) (Dezhou Kaiihang/Fengyu); *see also Certain Preserved Mushrooms From the People's Republic of China: Final Results of Antidumping Duty New Shipper Reviews* 76 FR 67146, (October 31, 2011) (Fujian Haishan/Hongda).

[5] Inter-Foods currently does not have separate rate status, and did not have separate rate status during the POR. Therefore, the Department did not send an inquiry to CBP with regard to Inter-Foods.

[6] To date, we have received no response from CBP related to any entries for Guangxi Jisheng. We intend to revisit our preliminary determination of no shipments for Guangxi Jisheng should any information provided by CBP warrant such reconsideration.

[7] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011).

[8] We note that the current rate in effect for the Guangxi Jisheng is the rate applicable to the PRC-wide entity.

[9] *See Initiation Notice* at 18207–08.

Methodology

The Department is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). For a full description of the methodology underlying our conclusions, please see the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and electronic versions of the Preliminary Decision Memorandum are identical in content.

Preliminary Results of the Review

On July 6, 2015, Kangfa withdrew from participation in this review prior to responding to the Department's questionnaire issued on June 10, 2015.[10] We therefore determine that Kangfa is ineligible for a separate rate and is part of the PRC-wide entity.[11]

Additionally, the Department preliminarily determines that the remaining 51 companies did not demonstrate their eligibility for separate rate status in this review because they have not filed either separate rate applications or separate rate certifications.[12] As a result, the Department is preliminarily treating these 51 companies as part of the PRC-wide entity.

The Department's change in policy regarding conditional review of the PRC-wide entity applies to this administrative review.[13] Under this policy, the PRC-wide entity will not be under review unless a party specifically requests, or the Department self-initiates, a review of the entity. Because no party requested a review of the PRC-wide entity in this review, the PRC-wide entity is not under review and therefore its rate is not subject to change. The rate previously established for the PRC-wide entity in this proceeding is 308.33 percent.[14]

Disclosure and Public Comment

Normally, the Department discloses to interested parties the calculations performed in connection with a preliminary results within five days of the date of publication of the notice of preliminary results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because the Department has preliminarily determined that Kangfa is ineligible for a separate rate, there are no calculations to disclose. Interested parties may submit case briefs no later than 30 days after the date of publication of the preliminary results.[15] Rebuttals to case briefs may be filed no later than five days after the deadline for filing case briefs and all rebuttal comments must be limited to comments raised in the case briefs.[16] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[17] Case and rebuttal briefs must be filed electronically via ACCESS.[18]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5:00 p.m. Eastern Time, within 30 days after the date of publication of this notice.[19] Hearing requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues parties intend to present at the hearing. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and location to be determined. Prior to the date of the hearing, the Department will contact all parties that submitted case or rebuttal briefs to determine if they wish to participate in the hearing. The Department will then distribute a hearing schedule to the parties prior to the hearing and only those parties listed on the schedule may present issues raised in their briefs.

Unless extended, the Department intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any briefs, within 120 days after the publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Assessment Rates

Upon issuing the final results of the review, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[20] The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of

[10] *See* July 6, 2015 letter from Kangfa to Secretary of Commerce: Re: Certain Preserved Mushrooms from China Withdrawal from Administrative Review (Kangfa Withdrawal Letter).

[11] *See* Preliminary Decision Memorandum; *Initiation Notice,* 80 FR at 18203 (providing that mandatory respondents will not be eligible for separate rate status ''unless they respond to all parts of the questionnaire as mandatory respondents.'').

[12] These 51 exporters are 1) Agrogentra & Co., Ltd., 2) Ayecue (Liaocheng) Foodstuff Co., Ltd, 3) Blue Field (Sichuan) Food Industrial Co., Ltd., 4) Casia Global Logistics Co., Ltd., 5) Changzhou Chen Rong- Da Carpet Co., Ltd., 6) China National Cereals, Oils & Foodstuffs Import & Export Corp., 7) China Processed Food Import & Export Co., 8) DHL ISC (Hong Kong) Limited, 9) Dujiangyan Xingda Foodstuff Co., Ltd., 10) Fujian Blue Lake Foods Co., Ltd., 11) Fujian Golden Banyan Foodstuffs Industrial Co., Ltd., 12) Fujian Pinghe Baofeng Canned Foods, 13) Fujian Yuxing Fruits and Vegetables Foodstuffs Development Co., Ltd., 14) Fujian Zishan Group Co., Ltd., 15) Guangxi Eastwing Trading Co., Ltd., 16) Guangxi Hengyang Industrial & Commercial Dev., Ltd., 17) Guangxi Hengyong Industrial & Commercial Dev. Ltd., 18) Inter-Foods (Dongshan) Co., Ltd., 19) Jiangxi Cereal Oils Foodstuffs, 20) Joy Foods (Zhangzhou) Co., Ltd., 21) Kangfa, 22) Longhai Guangfa Food Co., Ltd., 23) Primera Harvest (Xiangfan) Co., Ltd., 24) Shandong Jiufa Edible Fungus Corporation, Ltd., 25) Shandong Xinfa Agricultural Science Corporation Ltd., 26) Shandong Yinfeng Rare Fungus Corporation, Ltd., 27) Shenzhen Syntrans International Logistics Co., Ltd., 28) Sun Wave Trading Co., Ltd., 29) Sunrise Food Industry & Commerce, 30) Shouguang Sunrise Industry & Commerce Co., Ltd., 31) Thuy Duong Transport And Trading Service JSC, 32) Tianjin Fulida Supply Co., Ltd., 33) Xiamen Aukking Imp. & Exp. Co., Ltd., 34) Xiamen Carre Food Co., Ltd., 35) Xiamen Choice Harvest Imp., 36) Xiamen Greenland Import & Export Co., Ltd., 37) Xiamen Gulong Import & Export Co., Ltd., 38) Xiamen Huamin Imp. & Exp. Co., Ltd., 39) Xiamen Jiahua Import & Export Trading Co., Ltd., 40) Xiamen Longhuai Import & Export Co., Ltd., 41) Xiamen Longhuai Imp. & Exp. Co., Ltd., 42) Xiamen Longstar Lighting Co., Ltd., 43) Xiamen Sungiven Import & Export Co., Ltd., 44) Zhangzhou Golden Banyan Foodstuffs Industrial Co., Ltd., 45) Zhangzhou Long Mountain Foods Co., Ltd., 46) Zhangzhou Longhai Minhui Industry & Trade Co., Ltd., 47) Zhangzhou Tan Co., Ltd., 48) Zhangzhou Tongfa Foods Industry Co., Ltd., 49) Zhangzhou Yuxing Imp. & Exp. Trading Co., Ltd., 50) Zhejiang Iceman Food Co., Ltd., and 51) Zhejiang Iceman Group Co., Ltd.

[13] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65970 (November 4, 2013).

[14] *See Certain Preserved Mushrooms From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2013± 2014; and Partial Rescission of Review,* 80 FR 32355, 32357 (June 8, 2015).

[15] *See* 19 CFR 351.309(c)(1)(ii).

[16] *See* 19 CFR 351.309(d).

[17] *See* 19 CFR 351.309(c)(2) and (d)(2).

[18] *See* 19 CFR 351.303(b).

[19] *See* 19 CFR 351.310(c).

[20] *See* 19 CFR 351.212(b).

review. We intend to instruct CBP to liquidate relevant entries from the PRC-wide entity (including Kangfa) at the current rate for the PRC-wide entity (*i.e.,* 308.33 percent). For the companies identified above that were found to have made no shipments during the POR, we intend to instruct CBP to liquidate any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) at the PRC-wide rate.[21]

Cash Deposit Requirements

The following cash deposit requirements, when imposed, will apply to all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) For any previously reviewed or investigated PRC and non-PRC exporter not listed above that received a separate rate in a previous segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (2) for all PRC exporters that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the PRC-wide entity (*i.e.,* 308.33 percent); and (3) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied the non-PRC exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties. We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

[21] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

Dated: October 30, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2015–28340 Filed 11–5–15; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–475–833]

Countervailing Duty Investigation of Certain Corrosion-Resistant Steel Products From Italy: Preliminary Affirmative Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the ''Department'') preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain corrosion-resistant steel products (''corrosion-resistant steel'') from Italy. The period of investigation is January 1, 2014, through December 31, 2014. We invite interested parties to comment on this preliminary determination.

DATES: Effective November 6, 2015.

FOR FURTHER INFORMATION CONTACT: Bob Palmer, Irene Gorelik, and Katie Marksberry, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone 202.482.9068, 202.482.6905, and 202.482.7906, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Investigation

The products covered by this investigation are corrosion-resistant steel products from Italy. For a complete description of the scope of this investigation, see Appendix II.

Methodology

The Department is conducting this countervailing duty (''CVD'') investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the ''Act''). For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memo.[1] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memo is a public document and is on file electronically in the Central Records Unit, room B8024 of the main Department of Commerce building, as well as electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the CRU. In addition, parties can directly access a complete version of the Preliminary Decision Memo on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memo and the electronic versions of the Preliminary Decision Memo are identical in content.

Adverse Facts Available

Section 776(a) of the Act provides that, subject to section 782(d) of the Act, the Department shall apply ''facts otherwise available'' if: (1) Necessary information is not on the record; or (2) an interested party or any other person (A) withholds information that has been requested, (B) fails to provide information within the deadlines established, or in the form and manner requested by the Department, subject to subsections (c)(1) and (e) of section 782 of the Act, (C) significantly impedes a proceeding, or (D) provides information that cannot be verified as provided by section 782(i) of the Act. Furthermore, section 776(b) of the Act provides that the Department may use an adverse inference in applying the facts otherwise available when a party fails to cooperate by not acting to the best of its ability to comply with a request for information.

In this case, the Department twice requested information with respect to the *Industrial Development Grants Under Law 488/92, Technological Innovation Grants and Loans Under Law 46/82,* and *Certain Social Security*

[1] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Countervailing Duty Investigation of Certain Corrosion-Resistant Steel Products from Italy: Decision Memorandum for the Preliminary Determination,'' dated concurrently with this notice (''Preliminary Decision Memo'').

Reductions and Exemptions (``Sgravi'' Benefits) from the Government of Italy. The Government of Italy withheld necessary information with respect to each of these programs, failed to provide information in the form and manner requested, and did not provide requested information by the deadlines for submission of the information, as explained in more detail in the Preliminary Decision Memo. Furthermore, the Department has concluded that the Government of Italy did not cooperate to the best of its ability in providing the requested information. Accordingly, pursuant to sections 776(a) and (b) of the Act, we have preliminarily determined that for each of these programs, the application of adverse facts available is warranted. For the *Industrial Development Grants Under Law 488/92* and *Technological Innovation Grants and Loans Under Law 46/82* programs, we have preliminarily determined as adverse facts available that these programs are *de facto* specific, in accordance with section 771(5A)(D)(iii) of the Act. For the *Sgravi Benefits,* we have preliminarily determined that the reduced tax revenue due to the Government of Italy under these provisions constitute financial contributions within the meaning of section 771(5)(D)(ii) of the Act as revenue forgone. We have also preliminarily determined that revenue forgone under these provisions is either *de facto* specific, in accordance with section 771(5A)(D)(ii) of the Act, or regionally specific, in accordance with section 771(5A)(D)(iv) of the Act.

In addition, one company selected as a mandatory respondent, Ilva S.p.A., did not respond to the Department's questionnaires or participate in the investigation. Accordingly, as adverse facts available, pursuant to sections 776(a) and (b), we have preliminarily determined that Ilva benefitted from certain countervailable programs during the POI and calculated a rate for Ilva based on those programs. For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memo.

Preliminary Determination and Suspension of Liquidation

In accordance with section 703(d)(1)(A)(i) of the Act, we calculated an individual rate for each producer/exporter of the subject merchandise individually investigated. We preliminarily determine the countervailable subsidy rates to be:

Company	Subsidy rate (percent)
Acciaieria Arvedi S.p.A., Finarvedi S.p.A., Arvedi Tubi Acciaio S.p.A., Euro-Trade S.p.A., and Siderurgica Triestina Srl., collectively, the Arvedi Group.	0.38 (*de minimis*).
Marcegaglia S.p.A. and Marfin S.p.A., the Marcegaglia Group.	0.04 (*de minimis*).
Ilva S.p.A.	38.41.
All Others	13.06.

In accordance with section 703(d)(2) of the Act, we will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of corrosion-resistant from Italy as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, except for the Arvedi Group and the Marcegaglia Group, as described below. Section 703(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the later of (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered, or (b) the date on which notice of initiation of the investigation was published. On October 29, 2015, we preliminarily found that critical circumstances exist for imports produced or exported by Ilva S.p.A.[2] For Ilva S.p.A., in accordance with section 703(e)(2)(A) of the Act, suspension of liquidation of corrosion-resistant steel from Italy, as described in the ''Scope of the Investigation'' section, shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice, the date suspension of liquidation is first ordered. Because we preliminarily found critical circumstances do not exist for all other producers and exporters, we will begin suspension of liquidation for such firms on the date of publication of this notice in the **Federal Register**. Pursuant to 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit equal to the amounts indicated above. Further, because we reached a negative preliminary countervailing duty determination for the Arvedi Group and the Marcegaglia Group, we will not instruct CBP to suspend liquidation of entries for these companies.

In accordance with sections 703(d) and 705(c)(5)(A) of the Act, for companies not individually investigated, we apply an ''all-others'' rate, which is normally calculated by weighting the subsidy rates of the individual companies selected as mandatory respondents by those companies' exports of the subject merchandise to the United States. Under section 705(c)(5)(i) of the Act, the all-others rate excludes zero and *de minimis* rates calculated for the exporters and producers individually investigated as well as rates based entirely on facts otherwise available. Where the rates for the individually investigated companies are all zero or *de minimis,* or determined entirely using facts otherwise available, section 705(c)(5)(A)(ii) of the Act instructs the Department to establish an all-others rate using ''any reasonable method.'' Where the countervailable subsidy rates for all of the individually investigated respondents are zero or *de minimis* or are based on AFA, the Department's practice, pursuant to 705(c)(5)(A)(ii), is to calculate the all others rate based on a simple average of the zero or *de minimis* margins and the margins based on AFA. Notwithstanding the language of section 705(c)(5)(A)(i) of the Act, we have not calculated the ''all-others'' rate by weight averaging the rates of the two individually investigated respondents plus the margin based on AFA, because Ilva failed to report volume data that would enable the Department to determine the all-others rate based on a weighted-average. Therefore, and consistent with the Department's practice, for the ''all-others'' rate, we calculated a simple average of the two responding firms' rates and the AFA rate for the non-responsive company.[3]

Verification

As provided in section 782(i)(1) of the Act, we intend to verify the information submitted by the respondents prior to making our final determination.

[2] *See Antidumping and Countervailing Duty Investigations of Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Preliminary Determinations of Critical Circumstances,* 80 FR _____ (November ___, 2015) (signed October 29, 2015).

[3] *See, e.g., Countervailing Duty Investigation of Chlorinated Isocyanurates from the People's Republic of China: Preliminary Determination and Alignment of Final Determination With Final Antidumping Determination,* 79 FR 10097 (February 24, 2014); *see also, Non-Oriented Electrical Steel From Taiwan: Final Affirmative Countervailing Duty Determination,* 79 FR 61602 (October 14, 2014) and accompanying IDM at VIII. Calculation of the All Others Rate.

International Trade Commission Notification

In accordance with section 703(f) of the Act, we will notify the International Trade Commission (''ITC'') of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information relating to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Assistant Secretary for Enforcement and Compliance.

In accordance with section 705(b)(2) of the Act, if our final determination is affirmative, the ITC will make its final determination within 45 days after the Department makes its final determination.

Disclosure and Public Comment

The Department intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement.[4] Interested parties may submit case and rebuttal briefs,[5] and request a hearing.[6] For a schedule of the deadlines for filing case briefs, rebuttal briefs, and hearing requests, see the Preliminary Decision Memorandum.

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: November 2, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memo

[4] *See* 19 CFR 351.224(b).

[5] *See* 19 CFR 351.309(c) and (d).

[6] *See* 19 CFR 351.510.

Appendix II

The products covered by this investigation are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. The products covered include coils that have a width of 12.7 mm or greater, regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of 4.75 mm or more and a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.,* products which have been ''worked after rolling'' (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above, and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten (also called wolfram), or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels and high strength low alloy (HSLA) steels. If steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum.

Furthermore, this scope also includes Advanced High Strength Steels (AHSS) and Ultra High Strength Steels (UHSS), both of which are considered high tensile strength and high elongation steels.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Flat-rolled steel products either plated or coated with tin, lead, chromium, chromium oxides, both tin and lead (''terne plate''), or both chromium and chromium oxides (''tin free steel''), whether or not painted, varnished or coated with plastics or other non-metallic substances in addition to the metallic coating;
- Clad products in straight lengths of 4.7625 mm or more in composite thickness and of a width which exceeds 150 mm and measures at least twice the thickness; and
- Certain clad stainless flat-rolled products, which are three-layered corrosion-resistant flat-rolled steel products less than 4.75 mm in composite thickness that consist of a flat-rolled steel product clad on both sides with stainless steel in a 20%–60%–20% ratio.

The products subject to the investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7210.30.0030, 7210.30.0060, 7210.41.0000, 7210.49.0030, 7210.49.0091, 7210.49.0095, 7210.61.0000, 7210.69.0000, 7210.70.6030, 7210.70.6060, 7210.70.6090, 7210.90.6000, 7210.90.9000, 7212.20.0000, 7212.30.1030, 7212.30.1090, 7212.30.3000, 7212.30.5000, 7212.40.1000, 7212.40.5000, 7212.50.0000, and 7212.60.0000.

The products subject to the investigation may also enter under the following HTSUS item numbers: 7210.90.1000, 7215.90.1000, 7215.90.3000, 7215.90.5000, 7217.20.1500, 7217.30.1530, 7217.30.1560, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.91.0000, 7225.92.0000, 7225.99.0090, 7226.99.0110, 7226.99.0130, 7226.99.0180, 7228.60.6000, 7228.60.8000, and 7229.90.1000.

The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of the investigation is dispositive.

[FR Doc. 2015–28452 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–879]

Countervailing Duty Investigation of Certain Corrosion-Resistant Steel Products From the Republic of Korea: Preliminary Affirmative Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain corrosion-resistant steel products (corrosion-resistant steel) from the Republic of Korea (Korea). The period of investigation is January 1, 2014, through December 31, 2014. We invite interested parties to comment on this preliminary determination.

DATES: Effective November 6, 2015.

FOR FURTHER INFORMATION CONTACT: Myrna Lobo, or Jun Jack Zhao, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2371, and (202) 482–1396, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Investigation

The products covered by this investigation are corrosion-resistant steel products from Korea. For a complete description of the scope of this investigation, *see* Appendix II.

Methodology

The Department is conducting this countervailing duty (CVD) investigation in accordance with section 701 of the Act. For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.[1] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version are identical in content.

Preliminary Determination and Suspension of Liquidation

In accordance with section 703(d)(1)(A)(i) of the Act, we calculated a CVD rate for each individually investigated producer/exporter of the subject merchandise. For the programs found to be countervailable, we determined that there is a financial contribution and benefit, and that the resulting subsidy is specific, within the meaning of sections 771(5) and 771(5A) of the Act. Sections 703(d) and 705(c)(5)(A) of the Act state that for companies not individually investigated, we will determine an all-others rate, which is normally calculated by weight averaging the subsidy rates of the companies selected for individual investigation by those companies' exports of the subject merchandise to the United States. However, under section 705(c)(5)(A)(i) of the Act, the all-others rate may not include zero and *de minimis* rates or any rates based entirely on facts otherwise available. In this investigation, the only rate that is not *de minimis* or based entirely on facts otherwise available is the rate calculated for Dongbu Steel Co., Ltd./Dongbu Incheon Steel Co., Ltd. (Dongbu). Consequently, the rate calculated for Dongbu is also assigned as the ''all-others'' rate. We preliminarily determine the countervailable subsidy rates to be:

Company	Subsidy rate
Union Steel Manufacturing Co. Ltd./.	0.69 percent (*de minimis*).
Dongkuk Steel Mill Co., Ltd.	
Dongbu Steel Co., Ltd./ Dongbu Incheon Steel Co., Ltd.	1.37 percent.
All-Others	1.37 percent.

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, we will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of corrosion-resistant steel from Korea as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Pursuant to 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit equal to the rates indicated above for companies other than Union/Dongkuk. Section 703(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the later of (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered, or (b) the date on which notice of initiation of the investigation was published. On October 29, 2015, we preliminarily found that critical circumstances exist for imports produced or exported by the ''all-others'' companies. Accordingly, for the ''all-others'' category, in accordance with section 703(e)(2)(A) of the Act, suspension of liquidation of corrosion-resistant steel from Korea, as described in the ''Scope of the Investigation'' section, shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice, the date suspension of liquidation is first ordered. Because we find critical circumstances do not exist for Dongbu/Dongbu Incheon, we will begin suspension of liquidation for such firms on the date of publication of this notice in the **Federal Register**. Further, because we reached a preliminary negative determination for Union/Dongkuk, we will not instruct CBP to suspend liquidation of entries for this company.

Verification

As provided in section 782(i)(1) of the Act, we intend to verify the information submitted by the respondents prior to making our final determination.

International Trade Commission Notification

In accordance with section 703(f) of the Act, we will notify the International Trade Commission (ITC) of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information relating to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative

[1] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination: Countervailing Duty Investigation of Certain Corrosion-Resistant Steel Products from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

protective order, without the written consent of the Assistant Secretary for Enforcement and Compliance.

In accordance with section 705(b)(2) of the Act, if our final determination is affirmative, the ITC will make its final determination within 45 days after the Department makes its final determination.

Disclosure and Public Comment

The Department intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement.[2] Interested parties may submit case and rebuttal briefs, as well as request a hearing.[3] For a schedule of the deadlines for filing case briefs, rebuttal briefs, and hearing requests, *see* the Preliminary Decision Memorandum.

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: November 2, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

Appendix II

Scope of the Investigation

The products covered by this investigation are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. The products covered include coils that have a width of 12.7 mm or greater, regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of 4.75 mm or more and a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.,* products which have been ''worked after rolling'' (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above, and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten (also called wolfram), or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels and high strength low alloy (HSLA) steels. IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum.

Furthermore, this scope also includes Advanced High Strength Steels (AHSS) and Ultra High Strength Steels (UHSS), both of which are considered high tensile strength and high elongation steels.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Flat-rolled steel products either plated or coated with tin, lead, chromium, chromium oxides, both tin and lead (''terne plate''), or both chromium and chromium oxides (''tin free steel''), whether or not painted, varnished or coated with plastics or other non-metallic substances in addition to the metallic coating;
- Clad products in straight lengths of 4.7625 mm or more in composite thickness and of a width which exceeds 150 mm and measures at least twice the thickness; and
- Certain clad stainless flat-rolled products, which are three-layered corrosion-resistant flat-rolled steel products less than 4.75 mm in composite thickness that consist of a flat-rolled steel product clad on both sides with stainless steel in a 20%–60%–20% ratio.

The products subject to the investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7210.30.0030, 7210.30.0060, 7210.41.0000, 7210.49.0030, 7210.49.0091, 7210.49.0095, 7210.61.0000, 7210.69.0000, 7210.70.6030, 7210.70.6060, 7210.70.6090, 7210.90.6000, 7210.90.9000, 7212.20.0000, 7212.30.1030, 7212.30.1090, 7212.30.3000, 7212.30.5000, 7212.40.1000, 7212.40.5000, 7212.50.0000, and 7212.60.0000.

The products subject to the investigation may also enter under the following HTSUS item numbers: 7210.90.1000, 7215.90.1000, 7215.90.3000, 7215.90.5000, 7217.20.1500, 7217.30.1530, 7217.30.1560, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.91.0000, 7225.92.0000, 7225.99.0090, 7226.99.0110, 7226.99.0130, 7226.99.0180, 7228.60.6000, 7228.60.8000, and 7229.90.1000.

The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of the investigation is dispositive.

[FR Doc. 2015–28454 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See* 19 CFR 351.224(b).

[3] *See* 19 CFR 351.309(c)–(d), 19 CFR 351.310(c).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–027]

Countervailing Duty Investigation of Certain Corrosion-Resistant Steel Products From the People's Republic of China: Preliminary Affirmative Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain corrosion-resistant steel products (corrosion-resistant steel) from the People's Republic of China (PRC). The period of investigation is January 1, 2014, through December 31, 2014. We

invite interested parties to comment on this preliminary determination.

DATES: *Effective date:* November 6, 2015.

FOR FURTHER INFORMATION CONTACT: Emily Halle, David Lindgren, or Spencer Toubia, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–0176, (202) 482–3870, or (202) 482–0123, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Investigation

The products covered by this investigation are corrosion-resistant steel products from the PRC. For a complete description of the scope of this investigation, *see* Appendix II.

Methodology

The Department is conducting this countervailing duty (CVD) investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[1] For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.[2] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov*, and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed Preliminary Decision Memorandum and the electronic version are identical in content.

The Department notes that, in making these findings, we relied, in part, on facts available and, because we find that one or more respondents did not act to the best of their ability to respond to the Department's requests for information, we drew an adverse inference where appropriate in selecting from among the facts otherwise available.[3] For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum.

Preliminary Determination and Suspension of Liquidation

In accordance with section 703(d)(1)(A)(i) of the Act, we calculated an individual estimated countervailable subsidy rate for YPC.[4] Additionally, in accordance with sections 703(d) and 705(c)(5)(A) of the Act, for companies not individually investigated, we apply an ''all-others'' rate, which is normally calculated by weight averaging the subsidy rates of the companies selected for individual investigation by those companies' exports of the subject merchandise to the United States. However, under section 705(c)(5)(A)(i) of the Act, the all-others rate excludes zero and *de minimis* rates calculated for the exporters and producers individually investigated as well as rates based entirely on facts otherwise available. Therefore, we have excluded the rates based entirely on facts otherwise available assigned to Angang Group Hong Kong Company Ltd. (Angang), Baoshan Iron & Steel Co., Ltd. (Baoshan), Duferco S.A. (Duferco), Changshu Everbright Material Technology (Everbright), and Handan Iron & Steel Group (Handan) from the all-others rate. Because the only individually calculated rate that is not zero, *de minimis,* or based on facts otherwise available is the rate calculated for YPC, in accordance with section 705(c)(5)(A)(i) of the Act, the rate calculated for YPC is preliminarily assigned as the ''all-others'' rate. The preliminary estimated countervailable subsidy rates are summarized in the table below.

Company	Subsidy rate (percent)
Yieh Phui (China) Technomaterial Co., Ltd	26.26
Angang Group Hong Kong Company Ltd	235.66
Baoshan Iron & Steel Co., Ltd ...	235.66
Duferco S.A., Hebei Iron & Steel Group, and Tangshan Iron and Steel Group Co., Ltd	235.66
Changshu Everbright Material Technology	235.66
Handan Iron & Steel Group	235.66
All-Others	26.26

In accordance with section 703(d)(2) of the Act, we will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of corrosion-resistant steel from the PRC as described in the ''Scope of the Investigation'' entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Pursuant to 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit equal to the rests indicated above. Section 703(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the later of (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered, or (b) the date on which notice of initiation of the investigation was published. On October 29, 2015, we preliminarily found that critical circumstances exist for imports produced or exported by Angang, Baoshan, Duferco, Everbright, and Handan.[5] Accordingly, for these companies, in accordance with section 703(e)(2)(A) of the Act, suspension of liquidation of corrosion-resistant steel from the PRC, as described in the ''Scope of the Investigation,'' shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice, the date suspension of liquidation is first ordered. Because we find critical circumstances do not exist for YPC and for all-other producers and exporters, we will begin suspension of liquidation for such firms on the date of publication of this notice in the **Federal Register**.

[1] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Countervailing Duty Determination in the Countervailing Duty Investigation of Certain Corrosion-Resistant Steel Products from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[3] *See* sections 776(a) and (b) of the Act.

[4] The cooperating, individually-investigated exporter/producer is Yieh Phui (China) Technomaterial Co., Ltd. (YPC).

[5] *See Antidumping and Countervailing Duty Investigations of Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Preliminary Determination of Critical Circumstances,''* (signed October 29, 2015).

Verification

As provided in section 782(i)(1) of the Act, we intend to verify the information submitted by the respondents prior to making our final determination.

International Trade Commission Notification

In accordance with section 703(f) of the Act, we will notify the International Trade Commission (ITC) of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information relating to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Assistant Secretary for Enforcement and Compliance.

In accordance with section 705(b)(2) of the Act, if our final determination is affirmative, the ITC will make its final determination within 45 days after the Department makes its final determination.

Disclosure and Public Comment

The Department intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement.[6] Interested parties may submit case and rebuttal briefs, as well as request a hearing.[7] For a schedule of the deadlines for filing case briefs, rebuttal briefs, and hearing requests, *see* the Preliminary Decision Memorandum.

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: November 2, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

Appendix II—Scope of the Investigation

The products covered by this investigation are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. The products covered include coils that have a width of 12.7 mm or greater, regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of 4.75 mm or more and a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.,* products which have been ''worked after rolling'' (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above, and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten (also called wolfram), or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels and high strength low alloy (HSLA) steels. IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum.

Furthermore, this scope also includes Advanced High Strength Steels (AHSS) and Ultra High Strength Steels (UHSS), both of which are considered high tensile strength and high elongation steels.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Flat-rolled steel products either plated or coated with tin, lead, chromium, chromium oxides, both tin and lead (''terne plate''), or both chromium and chromium oxides (''tin free steel''), whether or not painted, varnished or coated with plastics or other non-metallic substances in addition to the metallic coating;
- Clad products in straight lengths of 4.7625 mm or more in composite thickness and of a width which exceeds 150 mm and measures at least twice the thickness; and
- Certain clad stainless flat-rolled products, which are three-layered corrosion-resistant flat-rolled steel products less than 4.75 mm in composite thickness that consist of a flat-rolled steel product clad on both sides with stainless steel in a 20%–60%–20% ratio.

The products subject to the investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7210.30.0030, 7210.30.0060, 7210.41.0000, 7210.49.0030, 7210.49.0091, 7210.49.0095, 7210.61.0000, 7210.69.0000, 7210.70.6030, 7210.70.6060, 7210.70.6090, 7210.90.6000, 7210.90.9000, 7212.20.0000, 7212.30.1030, 7212.30.1090, 7212.30.3000, 7212.30.5000, 7212.40.1000, 7212.40.5000, 7212.50.0000, and 7212.60.0000.

The products subject to the investigation may also enter under the following HTSUS item numbers: 7210.90.1000, 7215.90.1000, 7215.90.3000, 7215.90.5000, 7217.20.1500, 7217.30.1530, 7217.30.1560, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.91.0000, 7225.92.0000, 7225.99.0090, 7226.99.0110, 7226.99.0130, 7226.99.0180, 7228.60.6000, 7228.60.8000, and 7229.90.1000.

The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of the investigation is dispositive.

[FR Doc. 2015–28453 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See* 19 CFR 351.224(b).

[7] *See* 19 CFR 351.309(c)–(d), 19 CFR 351.310(c).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–274–806]

Melamine From Trinidad and Tobago: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Commerce.

SUMMARY: The Department of Commerce (''Department'') determines that melamine from the Republic of Trinidad and Tobago (''Trinidad and Tobago'') is being, or is likely to be, sold in the United States at less than fair value (''LTFV''), as provided in section 735 of the Tariff Act of 1930, as amended (''the Act''). The final weighted-average dumping margins for the investigation of melamine from Trinidad and Tobago are listed in the ''Final Determination'' section, *infra.*

DATES: *Effective:* November 6, 2015.

FOR FURTHER INFORMATION CONTACT: Laurel LaCivita, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4243.

SUPPLEMENTARY INFORMATION:

Background

On June 17, 2015, the Department published its *Preliminary Determination.*[1] We invited interested parties to comment on our *Preliminary Determination* of sales at LTFV. For a discussion of the events that occurred in this investigation subsequent to the *Preliminary Determination,* including parties' case and rebuttal briefs, *see* the Issues and Decision Memorandum.[2]

Period of Investigation

The period of investigation (''POI'') is October 1, 2013, through September 30, 2014. This period corresponds to the four most recent fiscal quarters prior to the month of the filing of the petition, which was November 2014.[3]

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (''CAS'') registry number 108–78–01, molecular formula $C_3H_6N_6$).[4] The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive. For a complete description of the merchandise subject to this investigation, *see* Appendix I.

Verification

As provided in section 782(i) of the Act, from June 13, 2015, to July 15, 2015, we conducted verifications of the sales and cost information submitted by Southern Chemical Corporation, Methanol Holdings (Trinidad) Limited (''MHTL'') and Helm Italia S.R.L.[5] We used standard verification procedures, including an examination of relevant accounting and production records and original source documents provided by respondents.[6]

Analysis of Comments Received

We addressed all issues raised by parties in case and rebuttal briefs in the Issues and Decision Memorandum, which is hereby adopted by this notice.[7] Appendix II to this notice includes a list of the issues which the parties raised and to which the Department responded in the Issues and Decision Memorandum. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''). ACCESS is available to registered users at *http://access.trade.gov.* The Issues and Decision Memorandum is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum is available at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Amended Preliminary Determination

Based on the Department's analysis of the comments received and our findings at verification, we made certain changes to MHTL's margin calculations. For a discussion of these changes, *see* the Issues and Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding any zero or *de minimis* margins, and margins determined entirely under section 776 of the Act. In this investigation, we calculated a weighted-average dumping margins for MHTL, the sole mandatory respondent, that was above *de minimis* and not based on section 776 of the Act. Accordingly, we have assigned MHTL's individually calculated margin as the all-others rate for this investigation.

Final Determination

The Department determines that the estimated final weighted-average dumping margins are as follows:

Producer and/or exporter	Weighted-average dumping margin (percent)
MHTL	172.53
All Others	172.53

Disclosure

We intend to disclose to parties the calculations performed in this proceeding within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (''CBP'') to continue to suspend liquidation of all appropriate entries of melamine from Trinidad and Tobago as described in the ''Scope of the Investigation'' section, which were entered, or withdrawn from warehouse, for consumption on or after June 17,

[1] *Melamine from Trinidad and Tobago: Affirmative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 80 FR 34621 (June 17, 2015) (''*Preliminary Determination*'').

[2] *See* Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Issues and Decision Memorandum for the Final Determination of Sales at Less than Fair Value in the Antidumping Duty Investigation of Melamine from Trinidad and Tobago,'' dated concurrently with this notice (''Issues and Decision Memorandum'').

[3] *See* 19 CFR 351.204(b)(1).

[4] Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6-triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names.

[5] *See* Memorandum to the File, ''Verification of the Cost Response of Methanol Holdings (Trinidad) Limited in the Antidumping Duty Investigation of Melamine from Trinidad and Tobago,'' dated July 31, 2015. *See also* Memorandum to the File, ''Antidumping Duty Investigation of Melamine from Trinidad and Tobago: Constructed Export Price, Home Market, and Third-Country Sales Verifications of Methanol Holdings (Trinidad) Limited, Southern Chemical Corporation and Helm Italia S.R.L.,'' dated September 10, 2015.

[6] *Id.*

[7] *See* Issues and Decision Memorandum.

2015, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination.*

Further, pursuant to 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit equal to the weighted-average amount by which normal value exceeds U.S. price as follows: (1) For the mandatory respondent listed above, the cash deposit rate will be equal to the dumping margin which the Department determined in this final determination adjusted, as appropriate, for export subsidies found in the final determination of the companion countervailing duty investigation; [8] (2) if the exporter is not a mandatory respondent identified in this investigation, but the producer is, the cash deposit rate will be the rate established for the producer of the subject merchandise; and (3) the cash deposit rates for all other producers or exporters will be 172.53 percent. The suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we notified the International Trade Commission (''ITC'') of the final affirmative determination of sales at LTFV. As the Department's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of melamine from Trinidad and Tobago, or sales (or the likelihood of sales) for importation, of melamine from Trinidad and Tobago. If the ITC determines that such injury does not exist, this proceeding will be terminated and all securities posted will be refunded or canceled. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

[8] In this case, although the product under investigation is also subject to a countervailing duty investigation, the Department found no countervailing duty determined to constitute an export subsidy. Therefore, we did not offset the cash deposit rates shown above for purposes of this determination.

Return or Destruction of Proprietary Information

This notice also serves as a reminder to the parties subject to administrative protective order (''APO'') of their responsibility concerning the disposition of propriety information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act.

Dated: October 30, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (''CAS'') registry number 108–78–01, molecular formula $C_3H_6N_6$).[9] Melamine is a crystalline powder or granule typically (but not exclusively) used to manufacture melamine formaldehyde resins. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II—Issues and Decision Memorandum

[9] Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6-triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names.

[FR Doc. 2015–28350 Filed 11–5–15; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–021]

Melamine From the People's Republic of China: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Commerce.

SUMMARY: The Department of Commerce (''Department'') determines that countervailable subsidies are being provided to producers and exporters of melamine from the People's Republic of China (''PRC''). For information on the estimated subsidy rates, see the ''Suspension of Liquidation'' section of this notice.

DATES: *Effective:* November 6, 2015.

FOR FURTHER INFORMATION CONTACT: Andrew Medley, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone 202–482–4987.

SUPPLEMENTARY INFORMATION:

Background

The petitioner to this investigation is Cornerstone Chemical Company (''Petitioner''). The Department selected five mandatory respondents; Far-Reaching Chemical Co., Ltd. (''Far-Reaching Chemical''), Zhongyuan Dahua Group Co., Ltd. (''Zhongyuan Dahua''), Qingdao Unichem International Trade Co., Ltd. (''Qingdao Unichem''), M and A Chemicals Corp China (''M&A Chemicals''), and Shandong Liaherd Chemical Industry Co., Ltd. (''Shandong Liaherd''). All five mandatory respondents and the Government of the PRC refused to participate in this investigation.

Period of Investigation

The period of investigation for which we are measuring subsidies is January 1, 2013, through December 31, 2013.

Case History

The Department published its *Preliminary Determination* on April 20, 2015.[1] In it, the Department applied an adverse inference to find that the programs on which the Department initiated this investigation and the programs which the Department subsequently included in this investigation pursuant to allegations made by Petitioner,[2] are countervailable. Further, the Department applied an adverse inference in its calculation of the *ad valorem* estimated countervailable subsidy rate for Far-Reaching Chemical, Zhongyuan Dahua, Qingdao Unichem, M&A Chemicals, and Shandong Liaherd. The Department invited, but did not receive, interested party comments on the *Preliminary Determination.* Thus, we have made no changes from the *Preliminary Determination* with respect to the determination to apply adverse inferences. However, as explained below, we made certain changes to the *ad valorem* final subsidy rate.

Also in the *Preliminary Determination,* pursuant to section 705(a)(1) of the Tariff Act of 1930, as amended (''the Act'') and 19 CFR 351.210(b)(4), we aligned the final countervailing duty (''CVD'') determination with the final antidumping duty (''AD'') determination. On July 2, 2015, the Department postponed the final AD determination (and, thus, the instant, aligned, CVD determination) until November 2, 2015.[3]

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (''CAS'') registry number 108–78–01, molecular formula $C_3H_6N_6$).[4] Melamine is a crystalline powder or granule typically (but not exclusively) used to manufacture melamine formaldehyde resins. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Use of Facts Otherwise Available, Including Adverse Inferences

For purposes of this final determination, we relied on facts available and applied an adverse inference, in accordance with sections 776(a) and (b) of the Act, with regard to (1) the existence of a financial contribution, benefit, and specificity for the alleged subsidy programs and (2) the net subsidy rates assigned to Far-Reaching Chemical, Zhongyuan Dahua, Qingdao Unichem, M&A Chemicals, and Shandong Liaherd. A full discussion of our decision to rely on adverse facts available (''AFA'') is presented in the Preliminary Decision Memorandum under the section ''Use of Facts Otherwise Available and Adverse Inferences.'' However, for this final determination we are making certain changes to the AFA rates.[5] Specifically, we are revising the AFA rates for ''Preferential Export Financing from the Export-Import Bank of China'' and ''Reduced Fee Export Insurance'' to reflect the highest calculated CVD rates for these programs.[6]

Suspension of Liquidation

In accordance with section 705(c)(1)(B)(i) of the Act, we have calculated individual rates for Far-Reaching Chemical, Zhongyuan Dahua, Qingdao Unichem, M&A Chemicals, and Shandong Liaherd. Section 705(c)(5)(A)(i) of the Act states that for companies not individually investigated, we will determine an ''all-others'' rate equal to the weighted average countervailable subsidy rates established for exporters and producers individually investigated, excluding any zero and *de minimis* countervailable rates, and any rates determined entirely under section 776 of the Act. Section 705(c)(5)(A)(ii) of the Act states that if the countervailable subsidy rates for all exporters and producers individually investigated are zero or *de minimis* rates, or are determined entirely under section 776 of the Act, the Department may use any reasonable method to establish an all-others rate for exporters and producers not individually investigated, including averaging the weighted average countervailable subsidy rates determined for the exporters and producers individually investigated. As described above, all of the mandatory respondents' subsidy rates were calculated entirely under section 776 of the Act. Therefore, we have resorted to ''any reasonable method'' to derive the ''all-others'' rate, as described under section 705(c)(5)(A)(ii) of the Act. We are basing the ''all-others'' rate on the simple average of the five rates determined for the mandatory respondents, consistent with section 705(c)(5)(A)(ii) of the Act.[7]

[1] *See Melamine From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination,* 80 FR 21706 (April 20, 2015) (''*Preliminary Determination*''), and the accompanying Preliminary Decision Memorandum.

[2] *See* the Department's memorandum entitled ''Countervailing Duty Investigation on Melamine from the People's Republic of China: January 27, 2015 New Subsidy Allegations,'' dated March 25, 2015.

[3] *See Melamine from the People's Republic of China: Postponement of Final Determination of Sales at Less Than Fair Value,* 80 FR 38175 (July 02, 2015).

[4] Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6-triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names.

[5] *See* Memorandum to the File titled ''Melamine from the People's Republic of China: Final Calculations,'' dated November 2, 2015.

[6] *Id. See also Countervailing Duty Investigation of Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Final Affirmative Determination, and Final Affirmative Critical Circumstances Determination, in Part,* 80 FR 34888 (June 18, 2015), and accompanying issues and decision memorandum (where we calculated a rate of 4.25 percent for the similar program ''Export Seller's Credits from the Export Import Bank of China''), unchanged in *Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order; and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 47902 (August 10, 2015).

[7] *See, e.g., Carbon and Certain Alloy Steel Wire Rod From the People's Republic of China: Final Affirmative Countervailing Duty Determination and Final Affirmative Critical Circumstances Determination,* 79 FR 68858 (November 19, 2014).

We determine the total estimated net countervailable subsidy rates to be:

Company	Subsidy rate (percent)
Far-Reaching Chemical Co., Ltd	154.00
M and A Chemicals Corp China	154.00
Qingdao Unichem International Trade Co., Ltd	154.00
Shandong Liaherd Chemical Industry Co., Ltd	[8] 156.90
Zhongyuan Dahua Group Co., Ltd	154.00
All Others	154.58

As a result of our *Preliminary Determination,* and pursuant to section 703(d) of the Act, we instructed U.S. Customs and Border Protection (''CBP'') to suspend liquidation of all entries of melamine from the PRC that were entered or withdrawn from warehouse, for consumption on or after April 20, 2015, the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, we issued instructions to CBP to discontinue the suspension of liquidation for CVD purposes for subject merchandise entered, or withdrawn from warehouse, on or after August 18, 2015, but to continue the suspension of liquidation of all entries from April 20, 2015, through August 17, 2015.

If the U.S. International Trade Commission (''ITC'') issues a final affirmative injury determination, we will issue a CVD order and reinstate the suspension of liquidation under section 706(a) of the Act and will require a cash deposit of estimated CVDs for such entries of merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms it will not disclose such information, either publicly or under an administrative protective order (''APO''), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Return or Destruction of Proprietary Information

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation that is subject to sanction.

This determination is published pursuant to sections 705(d) and 777(i) of the Act.

Dated: October 30, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–28351 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–DS–P

[8] *See* Preliminary Decision Memorandum at 7, where we explained that the AFA rate applicable to Shandong Liaherd includes additional grant programs applicable only to Shandong Liaherd based upon information contained in Shandong's Liaherd's financial statements. *See also* ''Initiation Checklist: Melamine from the People's Republic of China'' (December 2, 2014).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–274–807]

Melamine From Trinidad and Tobago: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Commerce.

SUMMARY: The Department of Commerce (the Department) determines that countervailable subsidies are being provided to a producer and exporter of melamine from Trinidad and Tobago. For more information on the estimated subsidy rate, *see* the ''Final Determination'' section of this notice.

DATES: *Effective:* November 6, 2015.

FOR FURTHER INFORMATION CONTACT: Kristen Johnson or Patricia Tran, Office III, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4793, or (202) 482–1503, respectively.

SUPPLEMENTARY INFORMATION:

Background

Petitioner in this investigation is Cornerstone Chemical Company. In addition to the Government of the Republic of Trinidad and Tobago, the mandatory respondent is Methanol Holdings (Trinidad) Ltd. (MHTL). The period of investigation for which we measured subsidies is January 1, 2013, through December 31, 2013.

Case History

The events that occurred in this investigation since the Department published the *Preliminary Determination* on April 20, 2015,[1] are discussed in the Final Decision Memorandum, which is hereby adopted by this notice.[2] The Final Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Final Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Final Decision Memorandum and the electronic version of the Final Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula $C_3H_6N_6$).[3] Melamine is a crystalline powder or granule typically (but not exclusively) used to manufacture melamine formaldehyde resins. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with

[1] *See Melamine from Trinidad and Tobago: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Determination,* 80 FR 21708 (April 20, 2015) *(Preliminary Determination*).

[2] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance regarding ''Issues and Decision Memorandum for the Final Affirmative Determination in the Countervailing Duty Investigation of Melamine from Trinidad and Tobago,'' dated concurrently with this notice (Final Decision Memorandum).

[3] Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6-triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names.

other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Analysis of Subsidy Programs and Comments Received

The Department has conducted this countervailing duty (CVD) investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). The subsidy programs under investigation, the changes we made since the *Preliminary Determination,* the issues raised in the case and rebuttal briefs filed by interested parties, and a full description of the methodology underlying our conclusions are discussed in the Final Decision Memorandum. A list of subsidy programs and the issues that parties raised is attached to this notice as an appendix.

Final Determination

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated a subsidy rate for MHTL, the only company subject to individual examination in this investigation. We determine that MHTL's total estimated net countervailable subsidy rate is 6.79 percent *ad valorem*.[4]

Section 705(c)(5)(A)(i) of the Act states that, for companies not individually investigated, we will determine an ''all others'' rate equal to the weighted-average countervailable subsidy rates established for exporters and producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act. Where the rates for investigated companies are zero or *de minimis,* or based entirely on facts otherwise available, section 705(c)(5)(A)(ii) of the Act instructs the Department to establish an ''all others'' rate using ''any reasonable method.'' As MHTL is the only company subject to individual examination in this investigation and its rate is not zero, *de minimis,* or based on facts otherwise available, we have assigned the 6.79 percent *ad valorem* rate calculated for MHTL as the ''all others'' rate in this investigation.

As a result of our *Preliminary Determination* and pursuant to section 703(d) of the Act, we instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of all entries of subject merchandise from Trinidad and Tobago, which were entered or withdrawn from warehouse, for consumption on or after April 20, 2015, the date of the publication of the *Preliminary Determination.* In accordance with section 703(d) of the Act, we later issued instructions to CBP to discontinue the collection of cash deposits and suspension of liquidation for CVD purposes for subject merchandise entered, or withdrawn from warehouse, on or after August 18, 2015, but to continue the collection of cash deposits and suspension of liquidation of all entries from April 20, 2015, through August 17, 2015.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order and reinstate the suspension of liquidation under section 706(a) of the Act and will require a cash deposit of estimated duties for such entries of merchandise in the amounts indicated above. However, if the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Return or Destruction of Proprietary Information

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation that is subject to sanction.

This determination is published pursuant to sections 705(d) and 777(i) of the Act.

Dated: October 30, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Final Decision Memorandum

[4] We intend to disclose to parties the calculations performed in this proceeding within five days of the public announcement of this notice in accordance with 19 CFR 351.224(b).

[FR Doc. 2015–28349 Filed 11–5–15; 8:45 am]
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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–020]

Melamine From the People's Republic of China: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Commerce.

SUMMARY: On June 18, 2015, the Department of Commerce (''Department'') published the preliminary determination of sales at less than fair value (''LTFV'') of melamine from the People's Republic of China (''PRC'').[1] The Department requested from interested parties, but did not receive, comments on the *Preliminary Determination*, which was based entirely on adverse facts available. The Department, thus, determines that melamine from the PRC is being, or is likely to be, sold in the United States at LTFV, as provided in section 735 of the Tariff Act of 1930, as amended (the ''Act''). The period of investigation (''POI'') is April 1, 2014, though September 30, 2014. The final weighted-average dumping margin of sales at LTFV is listed below in the ''Final Determinations'' section of this notice.

DATES: *Effective*: November 6, 2015.

FOR FURTHER INFORMATION CONTACT: James Terpstra, AD/CVD Operations, Office III, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3965.

SUPPLEMENTARY INFORMATION:

Background

On June 18, 2015, the Department published the *Preliminary Determination*.[2] In the *Preliminary Determination*, the Department found that the mandatory respondents did not establish their eligibility for a separate rate and were thus part of the PRC-wide entity. In addition, because the PRC-wide entity failed to cooperate to the best of its ability in complying with our requests for information, we preliminarily determined an estimated weighted-average dumping margin based on adverse facts available for the PRC-wide entity in accordance with section 776 of the Act and 19 CFR 351.308.[3] The Department invited all interested parties to provide comment on these findings. No interested party provided comments on our preliminary determination. Therefore, this final determination does not differ from the *Preliminary Determination.* On July 2, 2015, the Department postponed the final determination until November 2, 2015.[4]

Scope of the Order

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (''CAS'') registry number 108–78–01, molecular formula $C_3H_6N_6$).[5] Melamine is a crystalline powder or granule typically (but not exclusively) used to manufacture melamine formaldehyde resins. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of these investigations. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Separate Rate

In the *Preliminary Determination*, we determined that none of the exporters subject to this investigation demonstrated their eligibility for a separate rate and as such are part of the PRC-wide entity.[6] No party commented on this determination. As a result, for this final determination, we are continuing to treat these exporters as part of the PRC-wide entity and subject to the PRC-wide rate.

PRC-Wide Entity

In the *Preliminary Determination*, the Department assigned to the PRC-wide entity a rate of 363.31 percent based upon AFA.[7] Given that the Department did not receive any comments from interested parties, for this final determination, the Department continues to assign an AFA rate of 363.31 percent to the PRC-wide entity.

Final Determination

The Department determines that the estimated final weighted-average dumping margin is as follows:

Exporter	Weighted-average margin (percent)
PRC-Wide Entity[8]	363.31

Disclosure

Normally, the Department discloses to interested parties the calculations

[1] *See Melamine from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value,* 80 FR 34891 (June 18, 2015) (''*Preliminary Determination*'').

[2] *See Preliminary Determination* and accompanying Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, ''Decision Memorandum for Preliminary Determination of the Antidumping Duty Investigation of Melamine from the People's Republic of China,'' dated June 10, 2015 (''Preliminary Decision Memorandum'').

[3] *Id.*

[4] *See Melamine from the People's Republic of China: Postponement of Final Determination of Sales at Less Than Fair Value,* 80 FR 38175 (July 2, 2015).

[5] Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6-triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names.

[6] *See Preliminary Determination*, and accompanying Preliminary Decision Memorandum at 3–5.

[7] *See Preliminary Determination*, 80 FR at 34892.

[8] The PRC-wide entity includes the mandatory respondents Allied Chemicals Inc., Xinji Jiuyuan Chemical Co., Ltd., Sichuan Golden Elephant Sincerity Chemical Co., Ltd., and Zhongyuan Dahua Group Inc., which withdrew from the investigation prior to respondent selection. The PRC-wide entity also includes 26 exporters which received a quantity and value questionnaire from the Department but did not respond to the questionnaire. Those companies are: Anhui Jinhe Industrial Co., Ltd., Anhui Sunson Chemical Group Co., Ltd., Chengdu Yulong Chemical Co., Ltd., Fujian Sangang (Group), Hebei Jinglong Fengli Chemical Co., Ltd., Hefei Tianfeng Import & Export Co Ltd. China, Henan Zhongyuan Dahua Group Co., Ltd., JianFeng Chemicals, Jiangsu Heyou Group Co., Ltd., Jiangsu Sanmu Group Corporation, Kaiwei Investment Group, M and A Chemicals, Corp China, Nanjing Deju Trading Co Ltd. China, Nantong Zixin Industrial Co., Ltd., OCI Trading (Shanghai) Co., Ltd. China, Panjin Zhongrun Chemical Co., Ltd., Qingdao Shida Chemical Co., Ltd. China, Shandong Jinmei Mingshui Chemical Co., Ltd., Shandong Liaherd Chemical Industry Co., Ltd., Shandong Sanhe Chemical Company Ltd., Shandong Xintai Liaherd Chemical Co., Ltd., Shandong Yixing Melamine Co., Ltd., Sichuan Chemical Works Group Ltd., Sinopec Jinling Petrochemical Co., Ltd.,

Continued

performed within five days after the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because there are no changes to our *Preliminary Determination*, and because we continue to apply AFA to the PRC-wide entity, in accordance with section 776 of the Act, there are no final calculations to disclose.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (''CBP'') to continue to suspend liquidation of all imports of subject merchandise entered or withdrawn from warehouse, for consumption on or after June 18, 2015, the date of publication of the *Preliminary Determination* in the **Federal Register**. Pursuant to 19 CFR 351.205 (d), the Department will instruct CBP to require a cash deposit equal to the weighted-average amount by which the NV exceeds U.S. price, adjusted where appropriate for export subsidies,[9] as follows: (1) The rate for the exporters listed in the chart above will be the rate we have determined in this final determination; (2) for all PRC exporters of subject merchandise which have not received their own rate, the cash-deposit rate will be the PRC-wide rate; and (3) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash-deposit rate will be the rate applicable to the PRC exporter/producer combination that supplied that non-PRC exporter. These suspension-of-liquidation instructions will remain in effect until further notice.

As stated previously, we will adjust cash deposit rates by the amount of export subsidies, where appropriate. In this LTFV investigation, with regard to PRC-wide entity, export subsidies constitute 9.66 percent [10] of the final calculated countervailing duty rate in the concurrent countervailing duty investigation, and, thus, we will offset the PRC-wide rate of 363.31 percent by the countervailing duty rate attributable to export subsidies (*i.e.,* 9.66 percent) [11] to calculate the cash deposit rate for this LTFV investigation. We are not adjusting the PRC-wide rate for estimated domestic subsidy pass-through because we have no basis upon which to make such an adjustment.[12]

U.S. International Trade Commission (''ITC'') Notification

In accordance with section 735(d) of the Act, we will notify the ITC of our final determination of sales at LTFV. As our final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will, within 45 days, determine whether the domestic industry in the United States is materially injured, threatened with material injury, or the establishment of an industry in the United States is materially retarded by reason of imports or sales (or the likelihood of sales) for importation of the subject merchandise. If the ITC determines that material injury, threat of material injury, or material retardation does not exist, the proceeding will be terminated and all securities posted will be refunded or canceled. If the ITC determines that such injury, threat of injury, or retardation does exist, the Department will issue an antidumping duty order directing CBP to assess antidumping duties on all imports of the subject merchandise entered or withdrawn from warehouse for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Order (''APO'')

This notice also serves as a reminder to the parties subject to APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This determination and notice are issued and published in accordance with sections 735(d) and 777(i)(1) of the Act.

Dated: October 30, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–28352 Filed 11–5–15; 8:45 am]

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Well Hope Enterprises Limited, and Zhejiang Fuyang Yongxing Chemical Co., Ltd.

[9] *See* section 772(c)(1)(C) of the Act. Unlike in administrative reviews, the Department calculates the adjustment for export subsidies in investigations not in the margin calculation program, but in the cash deposit instructions issued to CBP. *See Notice of Final Determination of Sales at Less Than Fair Value, and Negative Determination of Critical Circumstances: Certain Lined Paper Products from India,* 71 FR 45012 (August 8, 2006), and accompanying Issues and Decision Memorandum at Comment 1.

[10] The following subsidy programs in the concurrent countervailing duty investigation are export subsidies: Preferential Export Financing from the Export-Import Bank of China (4.25%), Reduced Fee Export Insurance (4.25%), Grants to Cover Legal Fees in Trade Remedy Cases (0.58%), and Cash Grants for Exports (0.58%).

[11] *See* Melamine from the People's Republic of China: Final Affirmative Countervailing Duty Determination, dated concurrently with this notice.

[12] *See* Preliminary Decision Memorandum at the section, ''Section 777A(f) of the Act.''

DEPARTMENT OF COMMERCE

International Trade Administration

[C–583–857]

Countervailing Duty Investigation of Certain Corrosion-Resistant Steel Products From Taiwan: Preliminary Negative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are not being provided to producers and exporters of certain corrosion-resistent steel products (corrosion-resistant steel) from Taiwan. The period of investigation is January 1, 2014, through December 31, 2014. We invite interested parties to comment on this preliminary determination.

DATES: Effective November 6, 2015.

FOR FURTHER INFORMATION CONTACT: Joy Zhang or Cindy Robinson, Office III, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1168 and (202) 482–3797, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Investigation

The products covered by this investigation are corrosion-resistent steel products from Taiwan. For a complete description of the scope of the investigation, *see* Appendix II.

Methodology

The Department is conducting this countervailing duty (CVD) investigation in accordance with section 701 of the the Act. For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.[1] A list of topics discussed in the Preliminary Decision Memorandum is

[1] *See* Memorandum, ''Countervailing Duty Investigation of Certain Corrosion-Resistant Steel Products from Taiwan: Decision Memorandum for the Preliminary Negative Determination,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

New Subsidy Allegations

On October 1, 2015, the Department initiated an investigation of certain additional and new subsidy programs based on AK Steel's New Subsidy Allegations (NSA) with repect to Prosperity Companies,[2] Yieh Phui Companies,[3] and the Taiwan Authorities (TA).[4] We did not receive questionnaire responses from Prosperity Companies, the Yieh Phui Companies, and TA until October 16, 19, and 20, 2015, respectively.[5] The timing of the NSA questionnaire responses submitted by these parties does not give us sufficient time to incorporate them into our preliminary determination. We intend to examine these programs after the preliminary determination time permitting.[6]

Negative Preliminary Determination and Suspension of Liquidation

For this preliminary determination, we have calculated a *de minimis* countervailable subsidy rate for each individually investigated producer/exporter of the subject merchandise. Consistent with section 703(b)(4)(A) of the Act, we are disregarding these rates and preliminarily determine that no countervailable subsides are being provided to producers/exporters of the subject merchandise in Taiwan. Because the rates calculated for the individually investigated companies are *de minimis,* the all others rate is also *de minimis.*

We preliminarily determine the estimated countervailable subsidy rates to be:

Company	Subsidy rate
Prosperity Tieh Enterprise Co., Ltd. (PT); Hong-Ye Steel Co., Ltd. (HY); Prosperity Did Enterprise Co., Ltd. (PD); and Chan Lin Enterprise Co., Ltd. (CL) (collectively Prosperity Companies).	0.00 percent *ad valorem, de minimis*.
Yieh Phui Enterprise Co., Ltd. (Yieh Phui); Yieh Corporation Limited (YCL); Shin Yang Steel Co., Ltd. (Shin Yang); and Synn Industrial Co., Ltd (Synn) (collectively Yieh Phui Companies).	0.00 percent *ad valorem, de minimis*.
All Others	0.00 percent *ad valorem, de minimis*.

Because we preliminarily determine that the CVD rates in this investigation are *de minimis,* we will not direct CBP to suspend liquidation of entries of subject merchandise.

On October 29, 2015, we preliminarily found that, with regard to Taiwan, critical circumstances exist for imports of subject merchandise from ''All Other'' produers and exporters and did not exist for the mandatory respondents, the Prosperity Companies and the Yieh Phui Companies.[7] Thus, based on the *Preliminary Critical Circumstances Determination,* the retroactive collection of cash deposits would apply with regard to companies subject to the all others rate, contingent upon the Department reaching an affirmative result in the preliminary determination. As indicated in this notice and as further explained in the Preliminary Decision Memorandum, we have preliminarily determined that countervailable subsidies are not being provided to producers and exporters of corrosion-resistant steel from Taiwan and, thus, we are issuing a preliminary negative countervailing duty determination. Accordingly, we also preliminarily determine that critical circumstances do not exist with regard to imports of corrosion-resistant steel from Taiwan.

Verification

As provided in section 782(i)(1) of the Act, we intend to verify the information submitted by the respondents prior to making our final determination.

U.S. International Trade Commission Notification

In accordance with section 703(f) of the Act, we will notify the International Trade Commission (ITC) of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information relating to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Assistant Secretary for Enforcement and Compliance.

In accordance with section 705(b)(2) of the Act, if our final determination is affirmative, the ITC will make its final determination within 45 days after the Department makes its final determination.

Disclosure and Public Comment

The Department intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement.[8] Interested parties may submit case and rebuttal briefs, as well as request a hearing.[9] For a schedule of the deadlines for filing case briefs, rebuttal briefs, and hearing requests, *see* the Preliminary Decision Memorandum.

This determination is issued and published pursuant to sections 703(f)

[2] Including the mandatory respondent, Prosperity Tieh Enterprise Co., Ltd. (PT), and PT's following crossed-own affiliates: Hong-Ye Steel Co., Ltd. (HY), Prosperity Did Enterprise Co., Ltd. (PD), and Chan Lin Enterprise Co., Ltd. (CL) (collectively Prosperity Companies). *See* PT's initial questionnaire responses dated August 7, at 1–3.

[3] Including the mandatory respondent Yieh Phui Enterprise Co., Ltd. (Yieh Phui), and Yieh Phui's following crossed-own affiliates: Yieh Corporation Limited (YCL); Shin Yang Steel Co., Ltd. (Shin Yang); and Synn Industrial Co., Ltd (Synn).

[4] *See* Memorandum to Erin Begnal, ''Certain Corrosion-Resistant Steel (CORE) Products from Taiwan: Decision Memorandum on New Subsidy Allegations,'' dated October 1, 2015 (NSA Decision Memorandum).

[5] *See* Yieh Phui, PT, and TA's NSA questionnaire responses dated October 16, 2015, October 19, 2015, and October 20, 2015, respectively (NSAQR).

[6] *See* Preliminary Decision Memorandum for further details.

[7] *See Antidumping and Countervailing Duty Investigations of Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Preliminary Determinations of Critical Circumstances,* 80 FR _____ (November _____, 2015) (signed October 29, 2015) (*Preliminary Critical Circumstances Determination*).

[8] *See* 19 CFR 351.224(b).

[9] *See* 19 CFR 351.309(c)–(d), 19 CFR 351.310(c).

and 777(i) of the Act and 19 CFR 351.205(c).

Dated: November 2, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope Comments
IV. Scope of the Investigation
V. Preliminary Determination of Critical Circumstances
VI. Injury Test
VII. Subsidies Valuation
VIII. Benchmarks and Interest Rates
IX. Analysis of Programs
X. Disclosure and Public Comment
XI. Conclusion

Appendix II

Scope of the Investigation

The products covered by this investigation are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. The products covered include coils that have a width of 12.7 mm or greater, regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of 4.75 mm or more and a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.,* products which have been ''worked after rolling'' (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above, and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten (also called wolfram), or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels and high strength low alloy (HSLA) steels. IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum.

Furthermore, this scope also includes Advanced High Strength Steels (AHSS) and Ultra High Strength Steels (UHSS), both of which are considered high tensile strength and high elongation steels.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Flat-rolled steel products either plated or coated with tin, lead, chromium, chromium oxides, both tin and lead (''terne plate''), or both chromium and chromium oxides (''tin free steel''), whether or not painted, varnished or coated with plastics or other non-metallic substances in addition to the metallic coating;
- Clad products in straight lengths of 4.7625 mm or more in composite thickness and of a width which exceeds 150 mm and measures at least twice the thickness; and
- Certain clad stainless flat-rolled products, which are three-layered corrosionresistant flat-rolled steel products less than 4.75 mm in composite thickness that consist of a flat-rolled steel product clad on both sides with stainless steel in a 20%–60%–20% ratio.

The products subject to the investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7210.30.0030, 7210.30.0060, 7210.41.0000, 7210.49.0030, 7210.49.0091, 7210.49.0095, 7210.61.0000, 7210.69.0000, 7210.70.6030, 7210.70.6060, 7210.70.6090, 7210.90.6000, 7210.90.9000, 7212.20.0000, 7212.30.1030, 7212.30.1090, 7212.30.3000, 7212.30.5000, 7212.40.1000, 7212.40.5000, 7212.50.0000, and 7212.60.0000.

The products subject to the investigation may also enter under the following HTSUS item numbers: 7210.90.1000, 7215.90.1000, 7215.90.3000, 7215.90.5000, 7217.20.1500, 7217.30.1530, 7217.30.1560, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.91.0000, 7225.92.0000, 7225.99.0090, 7226.99.0110, 7226.99.0130, 7226.99.0180, 7228.60.6000, 7228.60.8000, and 7229.90.1000.

The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of the investigation is dispositive.

[FR Doc. 2015–28455 Filed 11–5–15; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–864]

Countervailing Duty Investigation of Certain Corrosion-Resistant Steel Products From India: Preliminary Affirmative Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''Department'') preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain corrosion-resistant steel products (''corrosion-resistant steel'') from India. The period of investigation is January 1, 2014, through December 31, 2014. We invite interested parties to comment on this preliminary determination.

DATES: Effective November 6, 2015.

FOR FURTHER INFORMATION CONTACT: Jerry Huang, Andrew Devine, or Matthew Renkey, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone 202.482.4047, 202.482.0238, and 202.482.2312, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Investigation

The products covered by this investigation are corrosion-resistant steel products from India. For a complete description of the scope of this investigation, *see* Appendix II.

Methodology

The Department is conducting this countervailing duty (''CVD'') investigation in accordance with section 701 of the Tariff Act of 1930, as amended (''Act''). For a full description

of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memo.[1] The Preliminary Decision Memo is a public document and is on file in the Central Records Unit (''CRU''), Room B8024 of the main Department of Commerce building, as well as electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the CRU. In addition, parties can directly access a complete version of the Preliminary Decision Memo on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memo and the electronic versions of the Preliminary Decision Memo are identical in content.

Preliminary Determination and Suspension of Liquidation

In accordance with section 703(d)(1)(A)(i) of the Act, we calculated an individual rate for each producer/exporter of the subject merchandise individually investigated. We preliminarily determine the countervailable subsidy rates to be:

Company	Subsidy rate (percent)
JSW Steel Limited and JSW Steel Coated Products Limited	2.85.
Uttam Galva Steels Limited and Uttam Value Steels Limited	7.71.
All Others	5.28.

In accordance with sections 703(d)(1)(B) and (d)(2) of the Act, we are directing U.S. Customs and Border Protection to suspend liquidation of all entries of corrosion-resistant steel from India that are entered, or withdrawn from warehouse, for consumption on or after the date of the publication of this notice in the **Federal Register**, and to require a cash deposit for such entries of merchandise in the amounts indicated above.

In accordance with sections 703(d) and 705(c)(5)(A) of the Act, for companies not investigated, we apply an ''all-others'' rate, which is normally calculated by weighting the subsidy rates of the individual companies selected as respondents by those companies' exports of the subject merchandise to the United States. Under section 705(c)(5)(i) of the Act, the all-others rate should exclude zero and *de minimis* rates calculated for the exporters and producers individually investigated. Where the rates for the investigated companies are all zero or *de minimis,* section 705(c)(5)(A)(ii) of the Act instructs the Department to establish an all-others rate using ''any reasonable method.'' We have not calculated the ''all-others'' rate by weight averaging the rates of the two individually investigated respondents, because doing so risks disclosure of proprietary information. Therefore, and consistent with the Department's practice, for the ''all-others'' rate, we calculated a simple average of the two responding firms' rates.[2]

Verification

As provided in section 782(i)(1) of the Act, we intend to verify the information submitted in response to the Department's questionnaires prior to making our final determination.

Disclosure and Public Comment

The Department intends to disclose calculations performed for this preliminary determination to the parties within five days of the date of public announcement of this determination in accordance with 19 CFR 351.224(b). Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the final verification report is issued in this proceeding, and rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[3] A table of contents, list of authorities used and an executive summary of issues should accompany any briefs submitted to the Department. This summary should be limited to five pages total, including footnotes.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5:00 p.m. Eastern Standard Time, within 30 days after the date of publication of this notice.[4] Requests should contain the party's name, address, and telephone number; the number of participants; and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a date, time and location to be determined. Parties will be notified of the date, time and location of any hearing.

International Trade Commission Notification

In accordance with section 703(f) of the Act, we will notify the International Trade Commission (''ITC'') of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information relating to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Assistant Secretary for Enforcement and Compliance.

In accordance with section 705(b)(2) of the Act, if our final determination is affirmative, the ITC will make its final determination within 45 days after the Department makes its final determination.

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: November 2, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memo

[1] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Countervailing Duty Investigation of Certain Corrosion-Resistant Steel Products from India: Decision Memorandum for the Preliminary Determination,'' dated concurrently with this notice (''Preliminary Decision Memo'').

[2] *See, e.g., Countervailing Duty Investigation of Chlorinated Isocyanurates from the People's Republic of China: Preliminary Determination and Alignment of Final Determination With Final Antidumping Determination,* 79 FR 10097 (February 24, 2014).

[3] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[4] *See* 19 CFR 351.310(c).

Appendix II—Scope of the Investigation

The products covered by this investigation are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. The products covered include coils that have a width of 12.7 mm or greater, regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of 4.75 mm or more and a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.,* products which have been ''worked after rolling'' (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above, and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this investigation are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten (also called wolfram), or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels and high strength low alloy (HSLA) steels. IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum.

Furthermore, this scope also includes Advanced High Strength Steels (AHSS) and Ultra High Strength Steels (UHSS), both of which are considered high tensile strength and high elongation steels.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this investigation unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Flat-rolled steel products either plated or coated with tin, lead, chromium, chromium oxides, both tin and lead (''terne plate''), or both chromium and chromium oxides (''tin free steel''), whether or not painted, varnished or coated with plastics or other non-metallic substances in addition to the metallic coating;
- Clad products in straight lengths of 4.7625 mm or more in composite thickness and of a width which exceeds 150 mm and measures at least twice the thickness; and
- Certain clad stainless flat-rolled products, which are three-layered corrosion-resistant flat-rolled steel products less than 4.75 mm in composite thickness that consist of a flat-rolled steel product clad on both sides with stainless steel in a 20%–60%–20% ratio.

The products subject to the investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7210.30.0030, 7210.30.0060, 7210.41.0000, 7210.49.0030, 7210.49.0091, 7210.49.0095, 7210.61.0000, 7210.69.0000, 7210.70.6030, 7210.70.6060, 7210.70.6090, 7210.90.6000, 7210.90.9000, 7212.20.0000, 7212.30.1030, 7212.30.1090, 7212.30.3000, 7212.30.5000, 7212.40.1000, 7212.40.5000, 7212.50.0000, and 7212.60.0000.

The products subject to the investigation may also enter under the following HTSUS item numbers: 7210.90.1000, 7215.90.1000, 7215.90.3000, 7215.90.5000, 7217.20.1500, 7217.30.1530, 7217.30.1560, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.91.0000, 7225.92.0000, 7225.99.0090, 7226.99.0110, 7226.99.0130, 7226.99.0180, 7228.60.6000, 7228.60.8000, and 7229.90.1000.

The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of the investigation is dispositive.

[FR Doc. 2015–28447 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request: Socioeconomics of Ocean Guardian Schools—An Office of the National Marine Sanctuaries Educational Program

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before January 5, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov).*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be

directed to Dr. Danielle Schwarzmann, 301–713–7254 or *danielle.schwarzmann@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a new information collection to provide benefit throughout the sanctuary system and specifically our sites that work with Ocean Guardian Schools. The National Ocean Service (NOS) proposes to collect information from parents and teachers about the attitudes and preferences and economic value they receive from being involved with an Ocean Guardian school.

Up-to-date socioeconomic data is needed to support the further development and improvement of Ocean Guardian Schools. These schools receive funding from the NOAA Office of Education and the Office of National Marine Sanctuaries. Schools may apply for funding up to five years. A number of schools have continued their Ocean Guardian School projects after the five years. From 2010–2015, the total funding received by 71 schools was $544,315.

Although the costs and sources of funding are known, there is limited information known about the economic value participants place on this program and the economic value created by these schools and their many activities. Currently, there is no information available that provides estimates of the value of education programs like Ocean Guardian to parents and teachers. Ocean Guardian Schools receive funding to develop projects to help protect the ocean in the future and promote ocean conservation and stewardship. Projects include recycling, beach clean-up days, installing rain barrels, installing wildlife structures, composting, and energy reduction.

The types of data targeted for this collection are: Attitudes and preferences towards the projects and student involvement, importance of/satisfaction with the program and attributes of the program, extent of reach (are parents aware of their student's involvement and are they too learning about ocean stewardship), level of teacher, student, parent and administrative involvement, and teachers' and parents' willingness to pay. The primary focus for the survey will be to gather data on parents' and teachers' willingness to pay for this program. Specifically, researchers will collect data to determine the economic value teachers, administrators and parents place on this program. The information collected will help to inform Ocean Guardian Schools about areas for improvement and the value that their programs create for the community.

II. Method of Collection

Respondents have a choice of either electronic or paper forms. Methods of submittal include email of electronic forms, and mail and facsimile transmission of paper forms.

III. Data

OMB Control Number: 0648–XXXX.

Form Number: None.

Type of Review: Regular submission (request for a new information collection).

Affected Public: State, local and tribal government, business or other for-profit organizations; not-for-profit institutions; individuals or households.

Estimated Number of Respondents: 60 teachers/other faculty; 900 parents.

Estimated Time per Response: 45 minutes per survey for teachers/other faculty; 20 minutes per survey for parents.

Estimated Total Annual Burden Hours: 342.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 2, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–28287 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE301

Western Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Western Pacific Fishery Management Council (Council) will convene a meeting of Habitat Areas of Particular Concern (HAPC) Working Group comprised of Fishery Ecosystem Plan Team members. The working group will explore and evaluate options in developing an HAPC designation process for the Western Pacific region.

DATES: The working group will meet on November 23, 2015. For specific times and agendas, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The HAPC working group meeting will be held at the Council office, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813; telephone: (808) 522–8220. WebEx and teleconference facilities will be provided for the meeting. The teleconference numbers are: U.S. toll-free: 1–888–482–3560 or International Access: +1 647 723–3959, and Access Code: 5228220; The web conference can be accessed at *https://wprfmc.webex.com/join/info.wpcouncilnoaa.gov*.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, Western Pacific Regional Fishery Management Council; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: HAPC working group members will explore different process options for designating Habitat Areas of Particular Concern in the Western Pacific Region. The purpose of this meeting is to evaluate process options to be consolidated into a report to the Council's Fishery Ecosystem Plan Team. A public comment period will be provided. The order in which agenda items are addressed may change. The meetings will run as late as necessary to complete scheduled business.

Schedule and Agenda for the HAPC Working Group Meeting

November 23, 2015Ð2 p.m.±4 p.m.

1. Introductions
2. HAPC Process Options
3. Evaluation
4. Public Comment

5. Other Business

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 3, 2015.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–28330 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE306

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Applications for three new scientific research permits and two permit renewals.

SUMMARY: Notice is hereby given that NMFS has received five scientific research permit application requests relating to Pacific salmon, steelhead, and eulachon. The proposed research is intended to increase knowledge of species listed under the Endangered Species Act (ESA) and to help guide management and conservation efforts. The applications may be viewed online at: *https://apps.nmfs.noaa.gov/preview/preview_open_for_comment.cfm.*

DATES: Comments or requests for a public hearing on the applications must be received at the appropriate address or fax number (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on December 7, 2015.

ADDRESSES: Written comments on the applications should be sent to the Protected Resources Division, NMFS, 1201 NE Lloyd Blvd., Suite 1100, Portland, OR 97232–1274. Comments may also be sent via fax to 503–230–5441 or by email to *nmfs.nwr.apps@noaa.gov* (include the permit number in the subject line of the fax or email).

FOR FURTHER INFORMATION CONTACT: Rob Clapp, Portland, OR (ph.: 503–231–2314), Fax: 503–230–5441, email: *Robert.Clapp@noaa.gov*). Permit application instructions are available from the address above, or online at *https://apps.nmfs.noaa.gov.*

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

The following listed species are covered in this notice:

Chinook salmon (*Oncorhynchus tshawytscha*): Lower Columbia River (LCR); threatened Puget Sound (PS).

Steelhead (*O. mykiss*): Threatened LCR; threatened PS.

Chum salmon (*O. keta*): Threatened Columbia River (CR).

Coho salmon (*O. kisutch*): Threatened LCR.

Eulachon (Thaleichthys pacificus): Threatened Southern (S) distinct population segment.

Authority

Scientific research permits are issued in accordance with section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et. seq*) and regulations governing listed fish and wildlife permits (50 CFR parts 222–226). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Anyone requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). Such hearings are held at the discretion of the Assistant Administrator for Fisheries, NMFS.

Applications Received

Permit 15582±2R

The City of Bothell, Washington is seeking to renew for five years a research permit that allows them to annually take juvenile PS Chinook salmon and PS steelhead. The purpose of the study is to develop a baseline and trend analysis to inform management decisions that could affect or be affected by stream water quality. These surveys would entail collecting macroinvertebrate samples and surveying streams for fish. The project would benefit listed salmonids by determining fish diversity in the monitored streams and generating information to help guide management decisions that would help remedy stream degradation. The researchers propose to capture fish using backpack electrofishing equipment and dip nets. The captured fish would be transferred to buckets via dip nets, anesthetized, identified by species, enumerated, measured, and released when recovered. The researchers do not propose to kill any listed fish, but a small number may die as an unintended result of the activities.

Permit 15611±2R

The Washington Department of Fish and Wildlife (WDFW) is seeking to renew for five years a permit that currently authorizes them to take adult LCR Chinook salmon, LCR steelhead, LCR coho salmon, and CR chum salmon while operating a fish collection facility on the North Fork Toutle River in Washington State. The fish collection facility is located at river mile 47.5, approximately 1.3 miles downstream from the Mount St. Helens sediment-retention structure. The purpose of the project is to trap and haul salmon and steelhead around the sediment retention structure. The WDFW would also collect scientific information and tag a portion of the fish to monitor migration patterns and spawning success. The primary benefit of the activities would be to allow listed salmon and steelhead to spawn in historically accessible habitat upstream of the sediment retention structure. The work would also benefit the fish by generating information on the species migration and spawning timing and location. The WDFW proposes to operate the trap several days a week during the species' upstream migration. Captured fish would be transported in a tanker truck and released upstream of the sediment retention structure. The WDFW does not intend to kill any fish being captured but some may die as an unintentional result of the activities.

Permit 18908

The Skagit Fisheries Enhancement Group (SFEG) has requested a five-year permit to annually take juvenile PS Chinook and PS steelhead in the Skagit River watershed. The purpose of the study is to help SFEG identify sites in need of restoration and target enhancement efforts. The project would benefit listed salmonids by helping guide projects designed to provide restored and high-quality rearing habitat. The SFEG proposes to capture fish using a beach seine and dip net. Fish captured in the seine (and kept in the water) would be removed using a small dip-net, quickly identified by species, and then immediately released into the water outside of the seine. The researchers do not propose to kill any of the listed fish being captured, but a small number may die as an unintended result of the activities.

Permit 19559

The AMEC Foster Wheel (AMECFW) is seeking a three-year research permit to annually take juvenile PS Chinook salmon and PS steelhead in the northern Puget Sound. The AMECFW research may also take adult S eulachon, for which there are currently no ESA take prohibitions. The researchers propose to use hydroacoustics to map herring school size and distribution from Point Whitehorn to Sandy Point (Whatcom County; WA). They would then use lampara seine/dip net surveys to confirm the species distribution and abundance information generated by the hydroacoustic surveys. The researchers may encounter a small number of listed salmonids and eulachon as bycatch in the netting/seining operations, but those animals would be released immediately without further handling or sampling. The researchers do not propose to kill any of the listed fish being captured, but a small number may die as an unintended result of the activities.

Permit 19738

The Washington Department of Natural Resources (WDNR) is seeking a five-year research permit to annually take juvenile PS Chinook salmon and PS steelhead in streams of northwest Puget Sound. The purpose of the study is to correctly type streams to ensure that riparian habitat buffers and fish passage structures adequately support or improve conditions for aquatic species, including listed salmonids. The WDNR proposes to capture fish using backpack electrofishing equipment. The captured fish would be counted, identified, measured and released. The researchers do not propose to kill any of the listed salmonids being captured, but a small number may die as an unintended result of the activities.

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate the applications, associated documents, and comments submitted to determine whether the applications meet the requirements of section 10(a) of the ESA and Federal regulations. The final permit decisions will not be made until after the end of the 30-day comment period. NMFS will publish notice of its final action in the **Federal Register**.

Dated: November 3, 2015.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–28333 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE303

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scientific & Statistical Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Monday, November 23, 2015, beginning at 9 a.m.

ADDRESSES:

Meeting address: The meeting will be held at the Hilton Garden Inn, Boston Logan, 100 Boardman Street, Boston, MA 02128; phone: (617) 567–6789.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will receive an update on the Council's groundfish catch advice project. There will be discussion of the Groundfish performance report as well as an update on progress of the Risk Policy Workgroup—receive a presentation on the draft road map for implementing a risk policy. They will also develop comments for Council consideration on proposed NOAA Fisheries EBFM policy. They will receive an update on Council activities related to EBFM. There will be a discussion on improving control rules for making acceptable biological catch (ABC) recommendations. They will discuss SSC organizational issues. They will consider other business as needed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 3, 2015.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–28331 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE305

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (Council) River Herring and Shad (RH/S) Committee will hold a public meeting to review recent developments in RH/S conservation and to consider potential RH/S activities for 2016.

DATES: The meeting will be held on Monday, November 23, 2015, from 1 p.m. to 4 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar. Webinar connection details will be available at: *http://www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their Web site at *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Council's River Herring and Shad Committee will meet Monday, November 23, 2015 at 1 p.m. to review

recent developments in RH/S conservation and consider potential RH/S activities for 2016. Specific topics may include, but would not be limited to: The NMFS River Herring Technical Expert Working Group (TEWG), voluntary RH/S bycatch reduction programs, RH/S catch data, lawsuits, river herring genetics studies, and studies on environmental drivers of river herring distribution. The Committee will also consider what 2016 actions may be appropriate to recommend to the Council, including the planned revisit of the RH/S Stock in the Fishery question, as well as whether new information suggests a revisit of potential time/area hotspot closures may be appropriate. Contact Jason Didden at (302) 526–5254 if you have questions about using a webinar to participate in a meeting.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: November 3, 2015.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–28332 Filed 11–5–15; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase from People Who are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds products to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective:* December 6,2015.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 6/12/2015 (80 FR 33485–33489), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and impact of the additions on the current or most recent contractors, the Committee has determined that the products listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products to the Government.

2. The action will result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products are added to the Procurement List:

Products

NSN(s)—Product Name(s):
- 5130–00–NIB–0075—3/8 Drive Shallow Standard, SAE 6 Point Fasteners, 12 Pieces
- 5130–00–NIB–0076—3/8 Drive Deep Standard, SAE 6 Point Fasteners, 12 Pieces
- 5130–00–NIB–0077—1/2 Drive Shallow Standard, SAE 6 Point Fasteners, 11 Pieces
- 5130–00–NIB–0078—1/2 Drive Deep Standard, SAE 6 Point Fasteners, 13 Pieces
- 5130–00–NIB–0079—3/8 Drive Shallow Metric, 6 Point Fasteners, 14 Pieces
- 5130–00–NIB–0080—3/8 Drive Deep Metric, 6 Point Fasteners, 14 Pieces
- 5130–00–NIB–0081—1/2 Drive Shallow Metric, 6 Point Fasteners, 15 Pieces
- 5130–00–NIB–0082—1/2 Drive Deep Metric, 6 Point Fasteners, 15 Pieces

Mandatory Purchase For: Broad Government Requirement
Mandatory Source(s) of Supply: Wiscraft, Inc., Milwaukee, WI
Contracting Activity: General Services Administration, Kansas City, MO
Distribution: B-List

NSN(s)—Product Name(s):
- 4240–00–NIB–0237—5' Illuminating Grip Wrap
- 4240–00–NIB–0238—10' Illuminating Grip Wrap
- 4240–00–NIB–0239—SCBA ID Tags
- 4240–00–NIB–0240—One-Sided Exit Sign, Silver Frame, Post Mount
- 4240–00–NIB–0241—Two-Sided Exit Sign, Silver Frame, Post Mount
- 4240–00–NIB–0242—One-Sided Exit Sign, Silver Frame, Wall Mount
- 4240–00–NIB–0243—One-Sided Exit Sign, No Frame, No Mount
- 4240–00–NIB–0244—25' Illuminating Tape
- 4240–00–NIB–0245—50' Illuminating Tape
- 4240–00–NIB–0246—25' Illuminating Tape with Arrows
- 4240–00–NIB–0247—50' Illuminating Tape with Arrows
- 4240–00–NIB–0248—Illuminating Helmet Band

Mandatory Purchase For: 100% of the requirements of the Department of Defense
Mandatory Source of Supply: Cincinnati Association for the Blind and Visually Impaired, Cincinnati, OH
Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA
Distribution: C-List

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2015–28326 Filed 11–5–15; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Addition and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed addition to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add a service to the Procurement List that will be provided by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products previously furnished by such agencies.

DATES: *Comments Must Be Received On Or Before:* 12/6/2015.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Addition

If the Committee approves the proposed addition, the entities of the Federal Government identified in this notice will be required to procure the service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following service is proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Service

Service Type: Help Desk Support Service.
Mandatory for: U.S. Army, Army Training Support Center, Combined Arms Center for Training, 3306 Wilson Avenue, Joint Base Langley-Eustis, VA.
Mandatory Source(s) of Supply: ServiceSource, Inc., Alexandria, VA.
Orion Career Works, Auburn, WA.
Contracting Activity: W6QM MICC–FDO, Ft Eustis, VA.

Deletions

The following products are proposed for deletion from the Procurement List:

Products

NSN(s)—Product Name(s):

7510–01–429–6946—DAYMAX System, Scratch Pad Refill, Lined, 6-hole.
7510–01–429–7418—DAYMAX System, Replacement Binder, LE, Zipper Closure, 3-hole, Burgundy.
7510–01–429–7414—DAYMAX System, Replacement Binder, LE, Zipper Closure, 3-hole, Black.
7510–01–429–7413—DAYMAX System, Replacement Binder, GLE, 7-hole, Black.
7510–01–429–7034—DAYMAX System, Tabbed Sections, 3-hole.
7510–01–429–7035—DAYMAX System, Itinerary Refill, 7-hole.
7510–01–429–7038—DAYMAX System, 'Things to Do' Refill, 3-hole.
7510–01–429–7040—DAYMAX System, Account Ledger Refill, 3-hole.
7510–01–429–7041—DAYMAX System, Assignment List Refill, DOD, 3-hole.
7510–01–429–7046—DAYMAX System, Account Ledger Refill, 7-hole.
7510–01–429–7050—DAYMAX System, Task Plan Refill, DOD, 3-hole.
7510–01–429–7051—DAYMAX System, Tabbed Alpha Directory, 3-hole.
7510–01–429–7052—DAYMAX System, DIA'Log' Refill, DOD, 3-hole.
7510–01–429–7053—DAYMAX System, Address Directory Refill, 3-hole.
7510–01–429–7059—DAYMAX System, Tabbed Alpha Directory, 7-hole.
7510–01–429–7063—DAYMAX System, Priority Tabs, DOD, 3-hole.
7510–01–429–7065—DAYMAX System, Agenda Refill, 3-hole.
7510–01–429–7066—DAYMAX System, Address Directory Refill, 7-hole.
7510–01–429–7068—DAYMAX System, Project Coordinator Refill, 3-hole.
7510–01–429–7069—DAYMAX System, Daily Coordinator Refill, DOD, 3-hole.
7510–01–429–7072—DAYMAX System, Project Coordinator Refill, 7-hole.
7510–01–429–7074—DAYMAX System, Agenda Refill, 7-hole.
7510–01–429–7076—DAYMAX System, Itinerary Refill, 3-hole.
7510–01–429–7081—DAYMAX System, Journal Refill, 3-hole.
7510–01–429–7412—DAYMAX System, Replacement Binder, IE, Velcro Closure, 3-hole, Burgundy.
7510–01–429–7415—DAYMAX System, Replacement Binder, IE, Velcro Closure, 3-hole, Black.
7510–01–429–7416—DAYMAX System, Replacement Binder, IE, Velcro Closure, 3-hole, Navy.
7510–01–429–7417—DAYMAX System, Replacement Binder, LE, Zipper Closure, 3-hole, Navy.
7510–01–429–7472—DAYMAX System, Replacement Binder, GLE, 7-hole, Burgundy.
7510–01–429–7474—DAYMAX System, Replacement Binder, GLE, 7-hole, Navy.
7510–01–429–7475—DAYMAX System, Replacement Binder, DOD Logo, 3-hole, Zipper Closure, Burgundy.
7510–01–429–7477—DAYMAX System, Replacement Binder, 7-hole, Zipper Closure, Woodland Camouflage.
7510–01–429–7835—DAYMAX System, Vinyl Zipper Pouch, 3-hole.
7510–01–429–7838—DAYMAX System, Tabbed Alpha Directory, 6-hole.
7510–01–429–7841—DAYMAX System, 'Things to Do' Refill, 7-hole.
7510–01–429–9609—DAYMAX System, Journal Refill, 7-hole.
7510–01–429–7843—DAYMAX System, Sheet Lifter, 3-hole.
7510–01–429–9985—DAYMAX System, Business/Credit Card Holder, 3-hole.
7510–01–429–9986—DAYMAX System, Ruler/Pagemark, 3-hole.
7510–01–463–0794—DAYMAX System, Sheet Lifter, 6-hole.
7510–01–463–0802—Logo, Customized, Silkscreen.
7510–01–485–6563—DAYMAX System, Sheet Lifter, 7-hole.
7510–01–485–6564—DAYMAX System, Vinyl Zipper Pouch, 7-hole.
7510–01–485–6565—DAYMAX System, Ruler/Pagemark, 7-hole.
7510–01–485–8334—DAYMAX System, Business/Credit Card Holder, 7-hole.
7510–01–463–0796—DAYMAX System, 'Things-To-Do' Refill, 6-hole.
7530–01–429–6938—DAYMAX System, Scratch Pad Refill, Lined, 3-hole.
7530–01–429–6940—DAYMAX System, Scratch Pad Refill, Lined, 7-hole.
7530–01–429–6948—DAYMAX System, Scratch Pad Refill, Graph, 3-hole.
7530–01–429–9505—DAYMAX System, Scratch Pad Refill, Graph, 7-hole.
7510–01–429–7043—DAYMAX System, Tabbed Sections, 7-hole.
7510–01–545–3775—DAYMAX System, 2014, Calendar Pad, Type II.
7510–01–545–3792—DAYMAX System, 2014, Calendar Pad, Type I.
7510–01–588–0116—DAYMAX System, 2014, Tabbed Monthly, JR, 6-hole.
7510–01–588–0120—DAYMAX System, 2015, Tabbed Monthly, JR, 6-hole.
7510–01–588–0132—DAYMAX System, 2014, Week at a View, GLE, 7-hole.
7510–01–588–0137—DAYMAX System, 2015, Week at a View, GLE, 7-hole.
7530–01–545–3737—DAYMAX System, 2014, Appointment Refill.
7530–01–545–3743—DAYMAX System, 2015, Appointment Refill.
7530–01–587- 9717—DAYMAX System, 2014, JR Deluxe Planner, 6-hole, Digital Camouflage.
7530–01–587- 9717L—DAYMAX System, 2014, JR Deluxe Planner, 6-hole, Digital Camouflage w/logo.
7510–01–588–0144—DAYMAX System, 2014, Month at a View, IE/LE, 3-hole.
7510–01–588–0149—DAYMAX System, 2014, Tabbed Monthly, IE/LE, 3-hole.
7510–01–588–0150—DAYMAX System, 2015, Month at a View, IE/LE, 3-hole.
7510–01–588–0153—DAYMAX System, 2015, Tabbed Monthly, IE/LE, 3-hole.
7510–01–588–0161—DAYMAX System, 2014, Day at a View, GLE, 7-hole.
7510–01–588–0163—DAYMAX System, 2015, Day at a View, GLE, 7-hole.
7510–01–588–0165—DAYMAX System, 2015, Month at a View, GLE, 7-hole.
7510–01–588–0167—DAYMAX System, 2015, Day at a View, IE/LE, 3-hole.
7510–01–588–0192—DAYMAX System, 2014, Week at a View, IE/LE, 3-hole.
7510–01–588–0182—DAYMAX System, 2014, Tabbed Monthly, GLE, 7-hole.
7510–01–588–0184—DAYMAX System, 2015, Tabbed Monthly, GLE, 7-hole.
7510–01–588–0190—DAYMAX System, 2014, Month at a View, GLE, 7-hole.
7510–01–588–0194—DAYMAX System, 2015, Week at a View, IE/LE, 3-hole.
7510–01–588–0200—DAYMAX System, 2014, Day at a View, IE/LE, 3-hole.
7530–01–587–9593—DAYMAX System, 2014, LE Planner, 3-hole, Burgundy.
7530–01–587–9593L—DAYMAX System, 2014, LE Planner, 3-hole, Burgundy w/ logo.
7530–01–587–9594—DAYMAX System, 2014, JR Planner, 6-hole, Burgundy.
7530–01–587–9594L—DAYMAX System, 2014, JR Planner, 6-hole, Burgundy w/ logo.
7530–01–587–9597—DAYMAX System, 2015, JR Planner, 6-hole, Burgundy.
7530–01–587–9597L—DAYMAX System, 2015, JR Planner, 6-hole, Burgundy w/ logo.
7530–01–587–9599—DAYMAX System, 2015, LE Planner, 3-hole, Burgundy.
7530–01–587–9599L—DAYMAX System, 2015, LE Planner, 3-hole, Burgundy w/ logo.
7530–01–587–9613—DAYMAX System, 2014, IE Planner, 3-hole, Burgundy.
7530–01–587–9613L—DAYMAX System, 2014, IE Planner, 3-hole, Burgundy w/ logo.
7530–01–587–9615—DAYMAX System,

2015, IE Planner, 3-hole, Navy.
7530–01–587–9615L—DAYMAX System, 2015, IE Planner, 3-hole, Navy w/logo.
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7530–01–587–9618L—DAYMAX System, 2015, IE Planner, 3-hole, Burgundy w/ logo.
7530–01–587–9708—DAYMAX System, 2014, LE Planner, 3-hole, Black.
7530–01–587–9708L—DAYMAX System, 2014, LE Planner, 3-hole, Black w/logo.
7530–01–587–9621—DAYMAX System, 2014, IE Planner, 3-hole, Black.
7530–01–587–9621L—DAYMAX System, 2014, IE Planner, 3-hole, Black w/logo.
7530–01–587–9622—DAYMAX System, 2015, IE Planner, 3-hole, Black.
7530–01–587–9622L—DAYMAX System, 2015, IE Planner, 3-hole, Black w/logo.
7530–01–587–9634—DAYMAX System, 2014, IE Planner, 3-hole, Navy.
7530–01–587–9634L—DAYMAX System, 2014, IE Planner, 3-hole, Navy w/logo.
7530–01–587–9643—DAYMAX System, 2014, GLE Planner, 7-hole, Burgundy.
7530–01–587–9643L—DAYMAX System, 2014, GLE Planner, 7-hole, Burgundy.
7530–01–587–9647—DAYMAX System, 2015, GLE Planner, 7-hole, Burgundy.
7530–01–587–9647L—DAYMAX System, 2015, GLE Planner, 7-hole, Burgundy w/ logo.
7530–01–587–9661—DAYMAX System, 2015, GLE Planner, 7-hole, Navy.
7530–01–587–9661L—DAYMAX System, 2015, GLE Planner, 7-hole, Navy w/logo.
7530–01–587–9678—DAYMAX System, 2014, GLE Planner, 7-hole, Black.
7530–01–587–9678L—DAYMAX System, 2014, GLE Planner, 7-hole, Black w/logo.
7530–01–587–9684—DAYMAX System, 2014, JR Deluxe Planner, 6-hole, Black.
7530–01–587–9684L—DAYMAX System, 2014, JR Deluxe Planner, 6-hole, Black w/logo.
7530–01–587–9685—DAYMAX System, 2015, GLE Planner, 7-hole, Black.
7530–01–587–9685L—DAYMAX System, 2015, GLE Planner, 7-hole, Black w/logo.
7530–01–587–9687—DAYMAX System, 2015, JR Deluxe Planner, 6-hole, Black.
7530–01–587–9687L—DAYMAX System, 2015, JR Deluxe Planner, 6-hole, Black w/logo.
7530–01–587–9705—DAYMAX System, 2014, JR Planner, 6-hole, Navy.
7530–01–587–9705L—DAYMAX System, 2014, JR Planner, 6-hole, Navy w/logo.
7530–01–587–9704—DAYMAX System, 2014, JR Planner, 6-hole, Black.
7530–01–587–9704L—DAYMAX System, 2014, JR Planner, 6-hole, Black w/logo.
7530–01–587–9706—DAYMAX System, 2015, JR Planner, 6-hole, Black.
7530–01–587–9706L—DAYMAX System, 2015, JR Planner, 6-hole, Black w/logo.
7530–01–587–9707—DAYMAX System, 2014, LE Planner, 3-hole, Navy.
7530–01–587–9707L—DAYMAX System, 2014, LE Planner, 3-hole, Navy w/logo.
7530–01–587–9709—DAYMAX System, 2015, JR Planner, 6-hole, Navy.
7530–01–587–9709L—DAYMAX System, 2015, JR Planner, 6-hole, Navy w/logo.
7530–01–587–9711—DAYMAX System, 2015, LE Planner, 3-hole, Black.
7530–01–587–9711L—DAYMAX System, 2015, LE Planner, 3-hole, Black w/logo.
7530–01–587–9712—DAYMAX System, 2015, LE Planner, 3-hole, Navy.
7530–01–587–9712L—DAYMAX System, 2015, LE Planner, 3-hole, Navy w/logo.
7530–01–587–9719—DAYMAX System, 2014, GLE Planner, 7-hole, Navy.
7530–01–587–9719L—DAYMAX System, 2014, GLE Planner, 7-hole, Navy w/logo.
7530–01–587–9720—DAYMAX System, 2015, JR Deluxe Planner, 6-hole, Digital Camouflage.
7530–01–587–9720L—DAYMAX System, 2015, JR Deluxe Planner, 6-hole, Digital Camouflage w/logo.
7530–01–587–9722—DAYMAX System, 2015, Planner, 7-hole, Desert Camouflage.
7530–01–587–9722L—DAYMAX System, 2015, Planner, 7-hole, Desert Camouflage w/logo.
7530–01–587–9731—DAYMAX System, 2014, Planner, 7-hole, Desert Camouflage.
7530–01–587–9731L—DAYMAX System, 2014, Planner, 7-hole, Desert Camouflage w/logo.
7530–01–588–0039—DAYMAX System, 2015, DOD Planner, 3-hole, Burgundy.
7530–01–588–0039L—DAYMAX System, 2015, DOD Planner, 3-hole, Burgundy w/ logo.
7530–01–588–0108—DAYMAX System, 2014, DOD Planner, 3-hole, Burgundy.
7530–01–588–0108L—DAYMAX System, 2014, DOD Planner, 3-hole, Burgundy w/ logo.
7530–01–588–0128—DAYMAX System, 2015, Planner, 7-hole, Woodland Camouflage.
7530–01–588–0128L—DAYMAX System, 2015, Planner, 7-hole, Woodland Camouflage w/logo.
7530–01–588–0122—DAYMAX System, 2014, Planner, 7-hole, Woodland Cam.
7530–01–588–0122L—DAYMAX System, 2014, Planner, 7-hole, Woodland Camouflage w/logo.
7510–01–565–8330—DAYMAX System, Replacement Binder, JR, Velcro Closure, 6-hole, Burgundy.
7510–01–565–8331—DAYMAX System, Replacement Binder, JR Deluxe, Zipper Closure, 6-hole, Digital Camouflage.
7510–01–565–8334—DAYMAX System, Business/Credit Card Holder, 6-hole.
7510–01–566–3925—DAYMAX System, Address Directory Refill, 6-hole.
7530–00–NSH–0099—DAYMAX System, Polyethylene Black Binder, 6 Ring.
7510–01–565–8332—DAYMAX System, Replacement Binder, JR Deluxe, Zipper Closure, 6-hole, Black Denier.
7510–01–565–8333—DAYMAX System, Replacement Binder, Zipper Closure, 7-hole, Desert Camouflage.
7510–01–565–8335—DAYMAX System, Replacement Binder, JR, Velcro Closure, 6-hole, Black.
7510–01–565–8336—DAYMAX System, Replacement Binder, JR, Velcro Closure, 6-hole, Navy.

Mandatory Source(s) of Supply: Easter Seals Western and Central Pennsylvania, Pittsburgh, PA.

Contracting Activity: General Services Administration, New York, NY.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2015–28325 Filed 11–5–15; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Intent To License Government-Owned Inventions; Intent To License on a Partially-Exclusive Basis

AGENCY: Department of the Army, DoD.

ACTION: Notice.

SUMMARY: The inventions listed below are assigned to the United States Government as represented by the Secretary of the Army. The U.S. Army Edgewood Chemical Biological Center intends to license these inventions on a partially-exclusive basis to Biodetech LLC, a Maryland corporation with principal offices at 2224 Choate Rd., Fallston, MD 21047. The inventions to be licensed collectively enable the Agents of Biological Origin Identifier (ABOid) system, and are disclosed in U.S. Patent 8,412,464, issued April 2, 2013 and entitled ''Methods for detection and identification of cell type'' and U.S. Patent 8,224,581, issued July 17, 2012 and entitled ''Methods for detection and identification of cell type.''

ADDRESSES: Requests for more information and/or objections should be directed to Jonathan Sampson, telephone: 410–436–3771, *jonathan.d.sampson.civ@mail.mil,* U.S. Army Edgewood Chemical Biological Center (ECBC), AMSRD–ECB–PI–BP–TT, Bldg. E3330/Rm. 241 5183 Blackhawk Road, APG, MD 21010–5424. Any requests or objections should be made within 15 days of the publication of this notice.

FOR FURTHER INFORMATION CONTACT: Amanda Yocum, Office of Research and Technology Applications, U.S. Army Edgewood Chemical Biological Center, AMSRD–ECB–PI–BP–TT, Bldg. E3330/Rm. 241 5183 Blackhawk Road, APG, MD 21010–5424, telephone: 410–436–5406, email: *amanda.l.yocum.civ@mail.mil.*

SUPPLEMENTARY INFORMATION: None.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2015–28215 Filed 11–5–15; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of the Army

Army Education Advisory Committee Meeting Notice

AGENCY: Department of the Army, DoD.

ACTION: Notice of open committee meeting.

SUMMARY: The Department of the Army is publishing this notice to announce the following Federal advisory committee meeting of the Army Education Advisory Committee. This meeting is open to the public.

DATES: The Army Education Advisory Committee will meet from 9:00 a.m. to 5:00 p.m. on December 2, 2015 and from 9:00 a.m. to 5:00 p.m. on December 3, 2015.

ADDRESSES: Army Education Advisory Committee, Lewis and Clark Center, 100 Stimson Ave., Bell Conference Room, Ft. Leavenworth, KS 66027.

FOR FURTHER INFORMATION CONTACT: Mr. Wayne Joyner, the Designated Federal Officer for the committee, in writing at ATTN: ATTG–ZC, TRADOC, 950 Jefferson Ave., Fort Eustis, VA 23604, by email at *albert.w.joyner.civ@mail.mil,* or by telephone at (757) 501–5810.

SUPPLEMENTARY INFORMATION: The committee meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to collect and analyze data dealing with how to blend the best characteristics of civilian and military educational institutions to create a premier learning environment, how the Army manages and assesses talent, and will finalize provisional subcommittee findings and recommendations.

Proposed Agenda: December 2–3: The committee is chartered to provide independent advice and recommendations to the Secretary of the Army on the educational, doctrinal, and research policies and activities of U.S. Army educational programs. The committee will review and evaluate information related to Army University, Talent Management, and how socio-cultural considerations can be embedded at all levels and in all domains of Army Leader Development. It will also discuss and deliberate provisional findings and recommendations from its subcommittees.

Public Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165, and subject to the availability of space, this meeting is open to the public. Seating is on a first to arrive basis. Attendees are requested to submit their name, affiliation, and daytime phone number seven business days prior to the meeting to Mr. Joyner, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section.

Because the meeting of the committee will be held in a Federal Government facility on a military base, security screening is required. A photo ID is required to enter base. Please note that security and gate guards have the right to inspect vehicles and persons seeking to enter and exit the installation. Lewis and Clark Center is fully handicap accessible. Wheelchair access is available in front at the main entrance of the building. For additional information about public access procedures, contact Mr. Joyner, the committee's Designated Federal Officer, at the email address or telephone number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Written Comments or Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the committee in response to the stated agenda of the open meeting or in regard to the committee's mission in general. Written comments or statements should be submitted to Mr. Joyner, the committee Designated Federal Officer, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. The Designated Federal Official will review all submitted written comments or statements and provide them to members of the committee for their consideration. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the Designated Federal Official at least seven business days prior to the meeting to be considered by the committee. Written comments or statements received after this date may not be provided to the committee until its next meeting. Pursuant to 41 CFR 102–3.140d, the Committee is not obligated to allow a member of the public to speak or otherwise address the Committee during the meeting. Members of the public will be permitted to make verbal comments during the Committee meeting only at the time and in the manner described below. If a member of the public is interested in making a verbal comment at the open meeting, that individual must submit a request, with a brief statement of the subject matter to be addressed by the comment, at least seven business days in advance to the committee's Designated Federal Official, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. The Designated Federal Official will log each request, in the order received, and in consultation with the committee Chair, determine whether the subject matter of each comment is relevant to the committee's mission and/or the topics to be addressed in this public meeting. A 15-minute period near the end of the meeting will be available for verbal public comments. Members of the public who have requested to make a verbal comment and whose comments have been deemed relevant under the process described above, will be allotted no more than three minutes during the period, and will be invited to speak in the order in which their requests were received by Designated Federal Official.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2015–28218 Filed 11–5–15; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of the Army

Final Environmental Impact Statement for the Schofield Generating Station Project, United States Army Garrison, Hawaii

AGENCY: Department of the Army, DoD.

ACTION: Notice of availability.

SUMMARY: The Department of the Army announces the availability of the Final Environmental Impact Statement (FEIS) for the proposed lease of land and granting of easements on Schofield Barracks and Wheeler Army Airfield to Hawaiian Electric Company (Hawaiian Electric) for the construction, ownership, operation, and maintenance of a 50-megawatt (MW) capacity, biofuel-capable generating station, referred to as the Schofield Generating Station, and associated power poles, high-tension power lines, and related equipment and facilities. In accordance with the National Environmental Policy Act (NEPA), the FEIS analyzes the environmental impacts associated with construction and operation of the

Schofield Generating Station and associated infrastructure.

DATES: No decision will be made until 30 days after publication of the NOA in the **Federal Register**.

ADDRESSES: A copy of the FEIS may be obtained by contacting: Department of the Army, Directorate of Public Works, United States Army Garrison, Hawaii ATTN: IMHW–PWE (L. Graham), 947 Wright Avenue, Wheeler Army Airfield, Schofield Barracks, Hawaii 96857–5013; or by email to *sgspcomments@tetratech.com.*

The FEIS can also be viewed at the following Web site: *http://www.garrison.hawaii.army.mil/schofieldplant.*

FOR FURTHER INFORMATION CONTACT: Please contact Ms. Lisa Graham, NEPA Coordinator, U.S. Army Garrison, Hawaii. Ms. Graham can be reached by phone at (808) 656–3075, or by email at *usaghi.comrel@gmail.com.*

SUPPLEMENTARY INFORMATION: The Proposed Action, referred to as the Schofield Generating Station Project (SGSP), consists of:

(1) The Army's lease of 8.13 acres of land and the related granting of a 2.5-acre interconnection easement on Schofield Barracks and Wheeler Army Airfield to Hawaiian Electric to construct, operate, and maintain a 50–MW capacity renewable energy generating station to include associated power poles, high-tension power lines, and related equipment and facilities.

(2) The State of Hawaii Department of Land and Natural Resources granting of a 1.28-acre easement and a 0.7-acre conservation district authorization to Hawaiian Electric allowing for the construction of a 46 kilovolt (kV) electrical power transmission line between the SGSP site and the existing Wahiawa Substation.

(3) Hawaiian Electric's construction, ownership, operation, and maintenance of a 50 MW capacity, biofuel-capable generating station and 46 kV sub-transmission line required to connect the Schofield Generating Station to the Hawaiian Electric grid.

The primary purpose of the Proposed Action is two-fold: To provide improved energy security to the U.S. Army Garrison, Hawaii at Schofield Barracks, Wheeler Army Airfield, and Field Station Kunia and to provide new secure, firm, flexible, and renewable energy generation to the grid on Oahu, Hawaii.

The needs for the Proposed Action are to increase energy security for the Army and Oahu; assist the Army in supporting renewable energy-related laws and Executive Orders and meeting its renewable energy goals; assist Hawaiian Electric in meeting the Hawaii Renewable Portfolio Standard goals; and improve future electrical generation on Oahu.

The electricity produced by the SGSP would normally supply power to all Hawaiian Electric customers through the island-wide electrical grid. During outages that meet the criteria specified in the Operating Agreement between the Army and Hawaiian Electric, SGSP output would first be provided to Army facilities at Schofield Barracks, Wheeler Army Airfield, and Field Station Kunia up to their peak demand of 32 MW, to meet their missions, and would additionally support the grid up to the station's full capacity. If there were a full island outage, the generating station could be used to restart other generating stations on the island.

Under the No Action Alternative, the Army would not lease the property or grant the easement and Hawaiian Electric would not construct and operate the SGSP.

The FEIS evaluates the impacts on land use; airspace use; visual resources; air quality, including climate and greenhouse gasses; noise; traffic and transportation; water resources; geology and soils; biological resources; cultural resources; hazardous and toxic substances; socioeconomics, including environmental justice; and utilities and infrastructure.

Impacts were assessed assuming full-time operation of the generating facility (24 hours a day, 365 days a year). Under normal conditions, the facility would likely operate less than full-time, so projected impacts could be less.

Anticipated impacts would be less than significant for all resources. All activities would fall within existing regulations, permits, and plans. Best management practices and design measures that would avoid or minimize adverse effects would be implemented for these resources: Visual, air quality, noise, traffic and transportation, water, geology and soils, biological resources, cultural resources, and hazardous and toxic substances.

Comments received on the Draft Environmental Impact Statement (DEIS) are addressed in the FEIS. Changes made to the text of the DEIS include minor additions and edits only. No substantive changes to the alternatives considered or the findings of the impact analysis were required or made.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2015–28223 Filed 11–5–15; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of the Army

Army Education Advisory Subcommittee Meeting Notice

AGENCY: Department of the Army, DoD.

ACTION: Notice of open subcommittee meeting.

SUMMARY: The Department of the Army is publishing this notice to announce the following Federal advisory committee meeting of the Defense Language Institute Foreign Language Center Board of Visitors, a subcommittee of the Army Education Advisory Committee. This meeting is open to the public.

DATES: The Defense Language Institute Foreign Language Center (DLIFLC) Board of Visitors Subcommittee will meet from 8:00 a.m. to 5:00 p.m. on December 2 and 3, 2015.

ADDRESSES: Defense Language Institute Foreign Language Center, Building 326, Weckerling Center, Presidio of Monterey, CA 93944.

FOR FURTHER INFORMATION CONTACT: Mr. Detlev Kesten, the Alternate Designated Federal Officer for the subcommittee, in writing at Defense Language Institute Foreign Language Center, ATFL–APAS–AA, Bldg. 634, Presidio of Monterey, CA 93944, by email at *detlev.kesten@dliflc.edu,* or by telephone at (831) 242–6670.

SUPPLEMENTARY INFORMATION: The subcommittee meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to provide the subcommittee with briefings and information focusing on DLIFLC issues and challenges.

Proposed Agenda: December 2—The subcommittee will receive briefings from DLIFLC personnel. The subcommittee will be updated on the Institute's accreditation. December 3—The subcommittee will have time to discuss and compile observations pertaining to agenda items. General deliberations leading to provisional findings will be referred to the Army Education Advisory Committee for deliberation by the Committee under the open-meeting rules.

Public Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165, and subject to the availability of space, this meeting is open to the

public. Seating is on a first to arrive basis. Attendees are requested to submit their name, affiliation, and daytime phone number seven business days prior to the meeting to Mr. Kesten, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Because the meeting of the subcommittee will be held in a Federal Government facility on a military base, security screening is required. A photo ID is required to enter base. Please note that security and gate guards have the right to inspect vehicles and persons seeking to enter and exit the installation. Weckerling Center is fully handicap accessible. Wheelchair access is available on the right side of the main entrance of the building. For additional information about public access procedures, contact Dr. Savukinas, the subcommittee's Alternate Designated Federal Officer, at the email address or telephone number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Written Comments or Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the subcommittee, in response to the stated agenda of the open meeting or in regard to the subcommittee's mission in general. Written comments or statements should be submitted to Mr. Kesten, the subcommittee Alternate Designated Federal Officer, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. The Alternate Designated Federal Official will review all submitted written comments or statements and provide them to members of the subcommittee for their consideration. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the Alternate Designated Federal Official at least seven business days prior to the meeting to be considered by the subcommittee. Written comments or statements received after this date may not be provided to the subcommittee until its next meeting. Pursuant to 41 CFR 102–3.140d, the Committee is not obligated to allow a member of the public to speak or otherwise address the Committee during the meeting. Members of the public will be permitted to make verbal comments during the Committee meeting only at the time and in the manner described below. If a member of the public is interested in making a verbal comment at the open meeting, that individual must submit a request, with a brief statement of the subject matter to be addressed by the comment, at least seven business days in advance to the subcommittee's Alternate Designated Federal Official, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. The Alternate Designated Federal Official will log each request, in the order received, and in consultation with the Subcommittee Chair, determine whether the subject matter of each comment is relevant to the Subcommittee's mission and/or the topics to be addressed in this public meeting. A 15-minute period near the end of the meeting will be available for verbal public comments. Members of the public who have requested to make a verbal comment and whose comments have been deemed relevant under the process described above, will be allotted no more than three minutes during the period, and will be invited to speak in the order in which their requests were received by the Alternate Designated Federal Official.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2015–28217 Filed 11–5–15; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF EDUCATION

Privacy Act of 1974, as Amended; Computer Matching Program between the U.S. Department of Education and the Social Security Administration

AGENCY: Department of Education.

ACTION: Notice.

SUMMARY: This document provides notice of the computer matching program between the U.S. Department of Education (ED) and the Social Security Administration (SSA). The computer matching program will begin on the effective date specified in paragraph 5.

SUPPLEMENTARY INFORMATION: This notice is provided under the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503) and the Computer Matching and Privacy Protection Amendments of 1990 (Pub. L. 101–508) (Privacy Act) (5 U.S.C. 552a); the Office of Management and Budget (OMB) Final Guidance Interpreting the Provisions of Public Law 100–503, the Computer Matching and Privacy Protection Act of 1988, 54 FR 25818 (June 19, 1989); and OMB Circular A–130, Appendix 1.

1. *Name of Participating Agencies.*

The U.S. Department of Education and the Social Security Administration.

2. *Purpose of the Match.*

The computer matching program will assist ED in its obligation to ensure that borrowers with disabilities who have loans under title IV of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1070 *et seq.*), more efficiently and effectively apply for total and permanent disability discharge of their student loans.

3. *Authority for Conducting the Matching Program.*

ED's legal authority to enter into this computer matching program and to disclose information as part of this computer matching program is section 437 of the HEA (20 U.S.C. 1087(a)), the regulations promulgated pursuant to that section (34 CFR 682.402(c)), and the Privacy Act (5 U.S.C. 552a(b)(3)).

SSA's legal authority to disclose information as part of this computer matching program is section 1106 of the Social Security Act (42 U.S.C. 1306), the regulations promulgated pursuant to that section (20 CFR. part 401), and the Privacy Act (5 U.S.C. 552a(b)(3)).

4. *Categories of Records and Individuals Covered by the Match.*

The records to be used in the match are described as follows:

ED will disclose to SSA the name, date of birth (DOB), and Social Security number (SSN) of individuals who owe a balance on one or more title IV, HEA loans, or who have a loan written off due to default from the system of records entitled ''National Student Loan Data System (NSLDS)'' (18–11–06), as last published in the **Federal Register** in full on June 28, 2013 (78 FR 38963–38969) and as last updated on April 2, 2014 (79 FR 18534–18536).

The ED data described in the preceding paragraph will be matched with SSA data recorded in the Disability Control File (DCF), which originate from the Supplemental Security Income Record and Special Veterans Benefits (SSR/SVB), 60–0103, published in the **Federal Register** on January 11, 2006 (71 FR 1830) and updated on December 10, 2007 (72 FR 69723), and the Master Beneficiary Record (MBR) SSA/ORSIS 60–0090, published on January 11, 2006 (71 FR 1826) and updated on December 10, 2007 (72 FR 69723) and on July 5, 2013 (78 FR 40542), in order to provide ED with Medical Improvement Not Expected disability data.

5. *Effective Date of the Matching Program.*

The effective date of the Computer Matching Agreement (CMA) and the date when the match may begin shall be whichever date is the latest of the following three dates: (1) The date of the last signatory to the CMA; (2) at the expiration of the 30-day public comment period following the publication of this matching program notice in the **Federal Register**; or (3) at the expiration of the 40-day period following ED's transmittal of a report concerning the matching program to OMB and to the appropriate Congressional Committees, along with a copy of the CMA, unless OMB waives 10 or fewer days of this 40-day review period for compelling reasons, in which case, 30 days plus whatever number of the 10 days that OMB did not waive from the date of the transmittal of the report to OMB and Congress. The matching program will continue for 18 months after the effective date and may be extended for an additional 12 months if the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met.

6. *Address for Receipt of Public Comments or Inquiries.*

Individuals wishing to comment on this matching program or obtain additional information about the program, including requesting a copy of the computer matching agreement between ED and SSA, may contact Lisa Oldre, Program Operations Specialist, Federal Student Aid, U.S. Department of Education, 830 First Street NE., Washington, DC 20202–5320. Telephone: 202–377–3249. As a secondary contact, individuals may contact Pam Eliadis, Service Director, System Operations & Aid Delivery Management, Federal Student Aid, U.S. Department of Education, 830 First Street NE., Washington, DC 20202–5320. Telephone: (202) 377–3554.

If you use a telecommunications device for the deaf or a text telephone, you may call the Federal Relay Service, toll free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an alternative format (*e.g.,* braille, large print, audiotape, or compact disc) on request to either contact person listed in the previous paragraph.

Electronic Access to the Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: The Privacy Act of 1974, as amended (5 U.S.C. 552a).

Dated: November 3, 2015.

James W. Runcie,

Chief Operating Officer, Federal Student Aid.

[FR Doc. 2015–28367 Filed 11–5–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP16–72–000.
Applicants: Texas Eastern Transmission, L.P.
Description: § 4(d) Rate Filing: Negotiated Rates—BP Energy contracts 911301 and 911302 to be effective 11/1/2015.
Filed Date: 10/26/15.
Accession Number: 20151026–5341.
Comments Due: 5 p.m. ET 11/9/15.

Docket Numbers: RP16–73–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Shell Energy Negotiated Rate to be effective 11/1/2015.
Filed Date: 10/27/15.
Accession Number: 20151027–5144.
Comments Due: 5 p.m. ET 11/9/15.

Docket Numbers: RP16–74–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Tenaska Marketing Negotiated Rate to be effective 11/1/2015.
Filed Date: 10/27/15.
Accession Number: 20151027–5150.
Comments Due: 5 p.m. ET 11/9/15.

Docket Numbers: RP16–75–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Occidental Energy Negotiated Rate to be effective 11/1/2015.
Filed Date: 10/27/15.
Accession Number: 20151027–5157.
Comments Due: 5 p.m. ET 11/9/15.

Docket Numbers: RP16–76–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 10/27/15 Negotiated Rates—MMGS Inc. (HUB) 7625–89 to be effective 11/1/2015.
Filed Date: 10/27/15.
Accession Number: 20151027–5232.
Comments Due: 5 p.m. ET 11/9/15.

Docket Numbers: RP16–77–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 10/27/15 Negotiated Rates—Emera Energy Services, Inc. (HUB) 2715–89 to be effective 11/1/2015.
Filed Date: 10/27/15.
Accession Number: 20151027–5244.
Comments Due: 5 p.m. ET 11/9/15.

Docket Numbers: RP16–78–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Munich Re Trading Negotiated Rate to be effective 11/1/2015.
Filed Date: 10/27/15.
Accession Number: 20151027–5247.
Comments Due: 5 p.m. ET 11/9/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 28, 2015

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–28299 Filed 11–5–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0692; FRL–9935–98]

Pesticide Experimental Use Permit; Receipt of Application; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's receipt of an application 91163–EUP–R from Texas Corn Producers Board requesting an experimental use permit (EUP) for the *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G. The Agency has determined that the permit may be of regional and national significance. Therefore, because of the potential significance, EPA is seeking comments on this application.

DATES: Comments must be received on or before December 7, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2015–0692, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. What action is the Agency taking?

Under section 5 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136c, EPA can allow manufacturers to field test pesticides under development. Manufacturers are required to obtain an EUP before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or one acre or more of water.

Pursuant to 40 CFR 172.11(a), the Agency has determined that the following EUP application may be of regional and national significance, and therefore is seeking public comment on the EUP application:

Submitter: Texas Corn Producers Board, (91163–EUP–R).

Pesticide Chemical: *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G.

Summary of Request: The applicant seeks permission to test an end-use product, FourSure, containing as active ingredients four strains of *Aspergillus flavus* (TC16F, TC35C, TC38B, and TC46G) to control aflatoxin on 4,500 acres/year of corn in Arkansas, Louisiana, Oklahoma, and Texas from 2016 to 2018.

Following the review of the application and any comments and data received in response to this solicitation, EPA will decide whether to issue or deny the EUP request, and if issued, the conditions under which it is to be conducted. Any issuance of an EUP will be announced in the **Federal Register**.

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 23, 2015.

Daniel J. Rosenblatt,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2015–28269 Filed 11–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9023–8]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www2.epa.gov/nepa.*

Weekly Receipt of Environmental Impact Statements (EISs)
Filed 10/26/2015 Through 10/30/2015
Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-nepa-public/action/eis/search.*

EIS No. 20150304, Draft, VA, SD, NHPA Section 106 Consultation: Reconfiguration of VA Black Hills Health Care System, Comment Period Ends: 01/05/2016, Contact: Luke Epperson 605–720–7170.

EIS No. 20150305, Draft, FERC, AK, Sweetheart Lake Hydroelectric Project-FERC Project No. 13563–003, Comment Period Ends: 12/29/2015, Contact: John Matkowski 202–502–8576.

EIS No. 20150306, Final, BLM, WAPA, NM, Southline Transmission Project, Review Period Ends: 12/07/2015, Contact: Mark Mackiewicz 435–636–6316.

The U.S. Department of the Interior's Bureau of Land Management and the U.S. Department of Energy's Western Area Power Administration are joint lead agencies for the above project.

EIS No. 20150307, Final, DOE, VT, New England Clean Power Link Project, Review Period Ends: 12/07/2015, Contact: Brian Mills 202–586–8267.

EIS No. 20150308, Final, USFWS, MA, Monomoy National Wildlife Refuge Comprehensive Conservation Plan, Review Period Ends: 12/07/2015, Contact: Nancy McGarigal 413–253–8562.

EIS No. 20150309, Draft, BIA, OK, Osage County Oil and Gas, Comment Period Ends: 12/21/2015, Contact: Jeannine Hale 918–781–4660.

EIS No. 20150310, Final, DOE, MN, Great Northern Transmission Line Project, Review Period Ends: 12/07/2015, Contact: Dr. Julie Ann Smith 202–586–7668.

EIS No. 20150311, Draft, GSA, DC, FBI Headquarters Consolidation, Comment Period Ends: 01/06/2016, Contact: Denise Decker 202–746–7891.

Amended Notices

EIS No. 20150303, Revised Final, USFS, NV, Greater Sage Grouse Bi-State Distinct Population Segment Forest Plan Amendment, Review Period Ends: 11/30/2015, Contact: James Winfrey 775–355–5308.

Revision to the FR Notice Published 10/30/2015; Correction to the EIS Status should be Revised Final.

Dated: November 3, 2015.

Karin Leff,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2015–28355 Filed 11–5–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0180]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 5, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0180.

Title: Section 73.1610, Equipment Tests.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents and Responses: 500 respondents; 500 responses.

Estimated Hours per Response: 0.5 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 250 hours.

Total Annual Cost: $0.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 154(i) of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: 47 CFR 73.1610 requires the permittee of a new broadcast station to notify the FCC of its plans to conduct equipment tests for the purpose of making adjustments and measurements as may be necessary to assure compliance with the terms of the construction permit and applicable engineering standards. FCC staff use the data to assure compliance with the terms of the construction permit and applicable engineering standards.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015–28303 Filed 11–5–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0920]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 5, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0920.

Title: Application for Construction Permit for a Low Power FM Broadcast Station; Report and Order in MM Docket No. 99–25 Creation of Low Power Radio Service; §§ 73.807, 73.809, 73.810, 73.827, 73.850, 73.865, 73.870, 73.871, 73.872, 73.877, 73.878, 73.318, 73.1030, 73.1207, 73.1212, 73.1230, 73.1300, 73.1350, 73.1610, 73.1620, 73.1750, 73.1943, 73.3525, 73.3550, 73.3598, 11.61(ii), FCC Form 318.

Form No.: FCC Form 318.

Type of Review: Extension of a currently approved collection.

Respondents: Not-for-profit institutions; State, local or Tribal governments.

Number of Respondents and Responses: 21,019 respondents with multiple responses; 27,737 responses.

Estimated Time per Response: .0025–12 hours.

Frequency of Response: Recordkeeping requirement; On occasion reporting requirement; Monthly reporting requirement; Third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in sections 154(i), 303, 308 and 325(a) of the Communications Act of 1934, as amended.

Total Annual Burden: 35,471 hours.

Total Annual Costs: $39,750.

Privacy Act Impact Assessment: This information collection does not affect individuals or households; thus, there are no impacts under the Privacy Act.

Nature and Extent of Confidentiality: There is no need for confidentiality with this information collection.

Needs and Uses: This submission is being made as an extension to an existing information collection pursuant to 44 U.S.C. 3507. This submission covers FCC Form 318 and its accompanying instructions and worksheets. FCC Form 318 is required: (1) To apply for a construction permit for a new Low Power FM (LPFM) station; (2) to make changes in the existing facilities of such a station; (3) to amend a pending FCC Form 318 application; or (4) to propose mandatory time-sharing.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015–28304 Filed 11–5–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–xxxx]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before January 5, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Approval Number: 3060–xxxx.

Title: Ensuring Continuity of 911 Communications Report and Order.

Form No.: N/A.

Type of Review: New information collection.

Respondents: Business or for profit.

Number of Respondents and Responses: 570 respondents; 570 responses.

Estimated Time per Response: 0–70 hours.

Frequency of Response: Initial point of sale disclosure and third party disclosure requirement which occurs on an annual basis.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in sections 1, 4(i), and 251(e)(3) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 251(e)(3); section 101 of the NET 911 Improvement Act of 2008, Pub. L. 110–283, 47 U.S.C. 615a–1; and section 106 of the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260, 47 U.S.C. 615c.

Total Annual Burden: 1,888 hours.

Total Annual Cost: No Cost.

Privacy Impact Assessment: No impact.

Nature and Extent of Confidentiality: The Commission is not requesting respondents to submit confidential information to the Commission.

Needs and Uses: We create new section 12.5 of our rules to place limited backup power obligations on providers of facilities-based fixed, residential voice services that are not line-powered to ensure that such service providers meet their obligation to provide access to 911 service during a power outage, and to provide clarity for the role of consumers and their communities should they elect not to purchase backup power.

Specifically, we require providers to disclose to subscribers the following information: (1) Availability of backup power sources; (2) service limitations with and without backup power during a power outage; (3) purchase and replacement options; (4) expected backup power duration; (5) proper usage

and storage conditions for the backup power source; (6) subscriber backup power self-testing and monitoring instructions; and (7) backup power warranty details, if any. Each element of this information must be given to subscribers both at the point of sale and annually thereafter, as described in the rule.

The disclosure requirements are intended to equip subscribers with necessary information to purchase and maintain a source of backup power to enhance their ability to maintain access to reliable 911 service from their homes.

We permit providers to convey both the initial and annual disclosures and information described above by any means reasonably calculated to reach the individual subscriber. For example, a provider may meet this obligation through a combination of disclosures via email, an online billing statement, or other digital or electronic means for subscribers that communicate with the provider through these means. For a subscriber that does not communicate with the provider through email and/or online billing statements—such as someone who ordered service on the phone or in a physical store and receives a paper bill by regular mail—email would not be a means reasonably calculated to reach that subscriber.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2015–28302 Filed 11–5–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 3, 2015.

A. Federal Reserve Bank of St. Louis (Yvonne Sparks, Community Development Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. *Republic Bancorp, Inc.,* Louisville, Kentucky; to acquire 100 percent of the voting shares of Cornerstone Bancorp, Inc., and thereby indirectly acquire voting shares of Cornerstone Community Bank, both in St. Petersburg, Florida.

Board of Governors of the Federal Reserve System, November 3, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–28324 Filed 11–5–15; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 23, 2015.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *The 2012 Clair J. Lensing Irrevocable Trust, Susan J. Elizondo GST-Exempt Under the Trust, James F. Lensing GST-Exempt Under the Trust, and Clair J. Lensing Jr. GST-Exempt Under the Trust, with Hills Bank & Trust Co., Hills, Iowa, as trustee; Susan Elizondo, Bettendorf, Iowa, James F. Lensing, Mason City, Iowa, and Clair J. Lensing Jr.,* Oelwein, Iowa, as beneficiaries, to join the Lensing Family Control Group and retain voting shares of Fayette Bancorporation, Marion, Iowa, and thereby indirectly retain voting shares of Citizens Savings Bank, Hawkeye, Iowa, Maynard Savings Bank, Maynard, Iowa, and Shell Rock Bancorporation, Shell Rock, Iowa, and thereby retain Security State Bank, Waverly, Iowa.

B. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Robert W. Frei,* Wagner, South Dakota; to join the Frei Family Group and to acquire voting shares of Commercial Holding Company, Wagner, South Dakota, and thereby indirectly acquire voting shares of Commercial State Bank, Wagner, South Dakota.

2. *The Voting Trust Agreement Among Certain Shareholders of NW Bancshares, Inc., Chippewa Falls, Wisconsin (``Colbert Family Voting Trust''), B. James Colbert, Chippewa Falls, Wisconsin, and Bradford J. Colbert III, Plymouth, Minnesota, individually and as trustees of the Colbert Family Voting Trust, and the following parties to the Colbert Family Voting Trust, the B. James Colbert Exempt QSST Trust, the Thomas John Despins Exempt QSST Trust, the Penny D. Jurss Exempt QSST Trust, the Bradford J. Colbert III Exempt QSST Trust, the Dee Dee A. Korth Exempt QSST Trust, and the Thomas James Despins Exempt QSST Trust, all of Chippewa Falls Wisconsin, (B. James Colbert and Bradford J. Colbert III, trustees); Thomas John Despins, De Pere, Wisconsin, Penny D. Jurss, Wales, Wisconsin, and the B. James Colbert and Kathryn M. Colbert Revocable Trust dated September 25, 2001, Kathryn M. Colbert,* individually and as trustee, both of Chippewa Falls, Wisconsin, as a group acting in concert, to acquire and retain voting shares of NW Bancshares, Inc., and thereby indirectly acquire and retain voting shares of The Northwestern Bank, both in Chippewa Falls, Wisconsin.

Board of Governors of the Federal Reserve System, November 3, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–28323 Filed 11–5–15; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than January 5, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Maternal and Child Health Bureau Performance Measures for Discretionary Grants

OMB No. 0915±0298—Revision.

Abstract: The Health Resources and Services Administration (HRSA) proposes to continue using reporting requirements for grant programs administered by MCHB, including national performance measures, previously approved by OMB, and in accordance with the ''Government Performance and Results Act (GPRA) of 1993'' (Pub. L. 103–62). This Act requires the preparation of an annual performance plan covering each program activity set forth in the agency's budget, which includes establishment of measurable goals and may be reported in an annual financial statement, which supports the linkage of funding decisions with performance. Performance measures for MCHB discretionary grants were initially approved in January 2003. Approval from OMB is being sought to continue the use of performance measures. Most of these measures are specific to certain types of programs and will not be required of all grantees. The measures will be categorized by domains (Adolescent Health, Capacity Building, Child Health, Children with Special Health Care Needs, Lifecourse/Crosscutting, Maternal/Women Health, and Perinatal/Infant Health). Grant programs would be assigned domains based on their activities.

Need and Proposed Use of the Information: The performance data will serve several purposes including grantee monitoring, program planning, performance reporting, and the ability to demonstrate alignment between MCHB discretionary programs and the MCH Title V Block Grant program. The overall number of performance measures has been reduced from what is currently used, and the structure of the system has been revised to better measure the various models of programs and the services each funded program provides. This revision will allow a more accurate and detailed picture of the full scope of services provided by grant programs administered by MCHB.

Likely Respondents: The grantees for Maternal and Child Health Bureau Discretionary Grant Programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Burden hours per response	Total burden hours
Grant Report	700	1	700	41	28,700

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–28264 Filed 11–5–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS) Full Committee Meeting.

Time and Date

November 18, 2015 8:30 a.m.–5:40 p.m. EST

November 19, 2015 8:15 a.m.–12:30 p.m. EST

Place: Centers for Disease Control and Prevention, National Center for Health Statistics, 3311 Toledo Road, Auditorium A and B, Hyattsville, Maryland 20782. (301) 458–4524.

Status: Open.

Purpose

At this meeting the Committee will hear presentations and hold discussions on several health data policy topics. The

Committee will hear updates from the Department, the Center for Medicare and Medicaid Services, and the Office of the National Coordinator focused on the Interoperability Roadmap. The Committee will review proceedings from the November 17, 2015, ''Workshop on Advancing Community-Level Core Measurement: Proposing a Roadmap for HHS'' held the day prior to the Committee meeting to determine next steps for the Population Health Subcommittee. In its designated role as the ACA Review Committee, the Standards Subcommittee will provide an update on preliminary findings and recommendations from the June 16–17, 2015 hearing on the status of adoption and implementation of HIPAA standards and operating rules. The Committee will review its strategic plan for 2016 and all Subcommittees will report on their workplans and next steps. In addition, the Committee will be briefed on and discuss the recent implementation of ICD–10. After the plenary session adjourns, the Working Group on HHS Data Access and Use will continue strategic discussions on building a framework for guiding principles for data access and use.

The times shown above are for the Full Committee meeting. Subcommittee issues will be included as part of the Full Committee schedule.

Contact Person for More Information: Substantive program information may be obtained from Rebecca Hines, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 6316, Hyattsville, Maryland 20782, telephone (301) 458–4715. Summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/*, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: October 28, 2015.

James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2015–28346 Filed 11–5–15; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS) Population Health Subcommittee Meeting.

Time and Date

November 17, 2015 8:30 a.m.–5:00 p.m. EST

Place: Centers for Disease Control and Prevention, National Center for Health Statistics, 3311 Toledo Road, Auditorium A and B, Hyattsville, Maryland 20782, (301) 458–4524.

Status: Open.

Purpose

On November 17, 2015, the NCVHS Population Health Subcommittee is holding a Workshop entitled ''Advancing Community-Level Core Measurement—Proposing a Roadmap for HHS.'' The Workshop objectives are to: Identify a balanced and parsimonious set of domains through which multi-sectoral community partnerships can assess, measure and improve local health and well-being, and; ultimately produce a proposed Roadmap for the Department of Health and Human Services to advance well-informed, community-driven action by promoting such set of domains along with suggested measures to facilitate greater availability and use of data within communities.

During the Workshop, participants will review the range of domains in current use for assessing community health and well-being with the aim of identifying a balanced set that encompasses the key determinants of health and that is consistent across all geographic levels. Recent efforts to streamline community health assessment have brought a new focus to the need to achieve parsimony in measuring health and well-being. This Workshop aims to leverage the momentum of both recent and long-standing projects by the IOM, Robert Wood Johnson Foundation (*e.g.,* Community Health Rankings), data intermediary organizations, federal agencies (*e.g.,* Community Health Status Indicators), state agencies, NCVHS, and others.

Contact Person for More Information: Substantive program information may be obtained from Rebecca Hines, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 6316, Hyattsville, Maryland 20782, telephone (301) 458–4715. Summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: October 28, 2015.

James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2015–28345 Filed 11–5–15; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5835–N–23]

60-Day Notice of Proposed Information Collection: Debt Resolution Program

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 5, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-

free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Michael Demarco, Director, Financial Operations Center, U.S. Department of HUD, 52 Corporate Circle, Albany, NY 12203, email at *Michael.C.DeMarco@hud.gov,* 1–800–669–5152 extension 2859. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Debt Resolution Program.

OMB Approval Number: 2502–0483.

Type of Request: Extension of currently approved collection.

Form Number: HUD–56141, HUD–56142 and HUD–56146.

Description of the need for the information and proposed use: HUD is required to collect debt owed to the agency. As part of the collection process, demand for repayment is made on the debtor(s). In response, debtors opt to ignore the debt, pay the debt or dispute the debt. Disputes and offers to repay the debt result in information collections. Borrowers who wish to pay the debt in installments must sign a written Repayment Agreement (HUD–56146). Borrowers who wish to pay less than the full amount due must submit a Personal Financial Statement (HUD–56142) and Settlement Offer (HUD–56141). HUD uses the information to analyze debtors' financial positions and then approve settlements and repayment agreements. Borrowers who wish to dispute must provide information to support their position.

Respondents: Individuals and household.

Estimated Number of Respondents: 650.

Estimated Number of Responses: 2101.

Frequency of Response: On occasion.

Average Hours per Response: one hour.

Total Estimated Burdens: 641.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: October 27, 2015.

Janet M. Golrick,

Associate General Deputy Assistant Secretary for Housing Associate Deputy Federal Housing Commissioner.

[FR Doc. 2015–28354 Filed 11–5–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5828–N–45]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has

decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: ENERGY: Mr. David Steinau, Department of Energy, Office of Property Management, OECM MA–50, 4B122, 1000 Independence Ave SW., Washington, DC 20585 (202) 287–1503; GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202) 501–0084; (These are not toll-free numbers).

Dated: October 29, 2015.

Norm Suchar,

Director, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 11/06/2015

Suitable/Available Properties

Building

Oregon

FAA Non Directional Becon
(NDB) sites on 0.92 acres
93924 Pitney Lane., Sec 6, T 16S R4W, W.M.
Junction City OR 97448
Landholding Agency: GSA
Property Number: 54201540009
Status: Unutilized
GSA Number: 9–OR–0806
Directions: Disposal Agency: GSA; Landholding Agency: FAA Tax Lot number 16040600; Lane County zoning is a 5 AC min. for residential (RR5)
Comments: 25+ yrs. old; 50 sq. ft.; storage; 24+ mos. vacant; poor condition; 0.92 acres of land; contact GSA for more information.

Unsuitable Properties

Building

Tennessee

2 Buildings
Y–12 National Security Complex
Oak Ridge TN 37831
Landholding Agency: Energy
Property Number: 41201540001
Status: Unutilized
Directions: 9828–01 and 9828–03
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

[FR Doc. 2015–28008 Filed 11–5–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCO956000 L14400000.BJ0000]

Notice of Filing of Plats of Survey; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey; Colorado.

SUMMARY: The Bureau of Land Management (BLM) Colorado State Office is publishing this notice to inform the public of the intent to officially file the survey plats listed below and afford a proper period of time to protest this action prior to the plat filing. During this time, the plats will be available for review in the BLM Colorado State Office.

DATES: Unless there are protests of this action, the filing of the plats described in this notice will happen on December 7, 2015.

ADDRESSES: BLM Colorado State Office, Cadastral Survey, 2850 Youngfield Street, Lakewood, CO 80215–7093.

FOR FURTHER INFORMATION CONTACT: Randy Bloom, Chief Cadastral Surveyor for Colorado, (303) 239–3856.

Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The plat and field notes of the dependent resurvey and survey in Township 46 North, Range 2 West, New Mexico Principal Meridian, Colorado, were accepted on October 6, 2015.

The plat incorporating the field notes of the dependent resurvey in the NW1/4 Section 35 in Township 12 South, Range 103 West, Sixth Principal Meridian, Colorado, was accepted on October 15, 2015.

The plat and field notes of the dependent resurvey and subdivision of sections in Township 2 South, Range 83 West, Sixth Principal Meridian, Colorado, were accepted on October 27, 2015.

Dale E. Vinton,

Acting Chief Cadastral Surveyor for Colorado.

[FR Doc. 2015–28315 Filed 11–5–15; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–CRPS–NAGPRA–19351; PPWOCRADN0, PCU00RP14.R50000 (166)]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Native American Graves Protection and Repatriation

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service, NPS) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This collection is set to expire on November 30, 2015. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number.

DATES: You must submit comments on or before December 7, 2015.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please also send a copy of your comments to Madonna L. Baucum, Information Collection Clearance Officer, National Park Service, 12201 Sunrise Valley Dr. (MS–242, Rm. 2C114), Reston, VA 20192 (mail); or *madonna_baucum@nps.gov* (email). Please reference OMB Control Number ''1024–0144'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: Melanie O'Brien, Manager, National NAGPRA Program, National Park Service, 1849 C Street NW., Washington, DC 20240; (202) 354–2204 (phone); (202) 371–5179 (fax); or *Melanie_O'Brien@nps.gov* (email). You may review the ICR online at *http://www.reginfo.gov*. Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Native American Graves Protection and Repatriation Act (NAGPRA), requires museums to compile certain information (summaries, inventories, and notices) regarding Native American cultural items in their possession or control. Museums must provide that information to lineal descendants; likely interested Indian tribes and Native Hawaiian organizations; and the National NAGPRA Program (acting on behalf of the Secretary of the Interior, housed in the National Park Service) to support consultation in the process of publishing notices that establish rights to repatriation. The summaries are general descriptions of the museum's Native American collection. The summaries are sent to all possibly interested tribes to disclose the collection, should the tribe desire to consult on items and present a claim. The inventories are item-by-item lists of the human remains and their funerary objects, upon which the museum consults with likely affiliated tribes to determine cultural affiliation, tribal land origination, or origination from aboriginal lands of Federal recognized tribes.

Consultation and claims for items require information exchange between museums and tribes on the collections. Notices of Inventory Completion (published in the **Federal Register**) indicate museum decisions of rights of lineal descendants and tribes to receive human remains and funerary objects. Notices of Intent to Repatriate (published in the **Federal Register**) indicate the agreements of museums and tribes to transfer control to tribes of funerary objects, sacred objects, and objects of cultural patrimony. Museums identify NAGPRA protected items in the collection through examination of museum records and from consultation with tribes.

The National NAGPRA Program maintains the public databases of summary, inventory, and notice information to support consultation. In the first 25 years of the administration of NAGPRA, approximately 50,000 Native American human remains, of a possible collection of over 200,000 individuals, have been listed in NAGPRA notices. Information collected in previous years is of lasting benefit, and creates diminishing efforts in future years.

II. Data

OMB Control Number: 1024–0144.

Title: Native American Graves Protection and Repatriation, 43 CFR part 10.

Type of Request: Extension of a previously approved collection of information.

Description of Respondents: Museums and tribes.

Respondent's Obligation: Mandatory.

Frequency of Collection: On occasion.

Activity	Annual respondents	Average time/ response	Total annual burden hours
New Summary/Inventory	3	100 hours	300
Updated Summary/Inventory Data	471	10 hours	4.710
Notices	105	10 hours	1,050
Notify Tribes and Request	14	30 minutes	7
Respond to Request for Information	16	48 minutes	13
Totals	609		6,080

Estimated Annual Nonhour Burden Cost: There are no nonhour burden costs associated with this collection.

III. Comments

On February 17, 2015, we published in the **Federal Register** (80 FR 8339) a notice of our intent to request that OMB renew approval for this information collection. In that notice, we solicited comments for 60 days, ending on April 20, 2015. We did not receive any comments in response to that notice.

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB and us in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: November 2, 2015.

Madonna L. Baucum

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2015–28318 Filed 11–5–15; 8:45 am]

BILLING CODE 4310–EH–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–19623; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before October 17, 2015, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by November 23, 2015.

ADDRESSES: Comments may be sent via U.S. Postal Service to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th Floor, Washington, DC 20005; or by fax, 202–371–6447.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before October 17, 2015. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

ALASKA

Anchorage Borough-Census Area

Wireless Station, The, 124, 132, 140 E. Manor Ave., Anchorage, 15000843

DELAWARE

Sussex County

Evans—West House, 40 West Ave., Ocean View, 15000844

DISTRICT OF COLUMBIA

District of Columbia

U.S. Department of Agriculture Administration Building (Boundary Increase and Additional Documentation), 12th St. & Jefferson Dr., SW., Washington, 15000845

GUAM

Guam County

U.S. Naval Cemetery, Marine Corps Dr., Hagatna, 15000846

HAWAII

Honolulu County

Guard, J.B., House, 305A Portlock Rd., Honolulu, 15000847

LOUISIANA

East Baton Rouge Parish

Union Federal Savings and Loan Association, (Architecture of A. Hays Town in Louisiana MPS) 500 Laurel St., Baton Rouge, 15000848

MINNESOTA

Hennepin County

Schmid Farmhouse Ruin, (Minnesota's Nineteenth-Century Masonry Ruins MPS) .38 mi. NE. of jct. of Cty Rd. 44 and CSAH 7, Minnetrista, 15000849

NEW JERSEY

Camden County

Cooper Grant Historic District (Boundary Increase), 300 N. Delaware Ave., Camden, 15000850

NEW MEXICO

Santa Fe County

Petroglyph Hill, (Ancestral Puebloan and Spanish Colonial Landscapes in the Greater Galisteo Basin MPS) Address Restricted, Galisteo, 15000851

NEW YORK

Lewis County

Beaver Falls Grange Hall No. 554, 9577 Main St., Beaver Falls, 15000852

Schenectady County

St. Columba School, 400 Craig St., Schenectady, 15000853

Young Men's Christian Association of Schenectady, 9–13 State St., Schenectady, 15000854

Schoharie County

Miers, Jacob T., House, 103 Knower Ave., Schoharie, 15000857

PUERTO RICO

Naguabo Municipality

Icacos Petroglyph Group, (Prehistoric Rock Art of Puerto Rico MPS) Address Restricted, Naguabo, 15000855

WYOMING

Natrona County

Turner—Cottman Building, 120–130 W. 2nd St., Casper, 15000856

Sweetwater County

Bairoil Town Hall, 505 Antelope Dr., Bairoil Dr., 15000858

A request to move has been received for the following resources:

COLORADO

El Paso County

Rio Grande Engine No. 168, 9 S. Sierra Madre, Colorado Springs, 79000601

MINNESOTA

Washington County

Bergstein, Moritz, Shoddy Mill and Warehouse, 6046 Stagecoach Rd., Oak Park Heights, 08000133

A request for removal has been received for the following resource:

WYOMING

Laramie County

Corlett School, 600 W. 22nd St., Cheyenne, 05000702

Authority: 60.13 of 36 CFR part 60

Dated: October 20, 2015.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

[FR Doc. 2015–28295 Filed 11–5–15; 8:45 am]

BILLING CODE 4312–51–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Wearable Activity Tracking Devices, Systems, and Components Thereof, DN 3096;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at EDIS,[1] and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at USITC.[2] The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at EDIS.[3] Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Fitbit, Inc. on November 2, 2015. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain wearable activity

[1] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[2] United States International Trade Commission (USITC): *http://edis.usitc.gov.*

[3] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

tracking devices, systems, and components thereof. The complaint names as respondents AliphCom d/b/a Jawbone of San Francisco, CA and BodyMedia, Inc. of Pittsburgh, PA. The complainant requests that the Commission issue a limited exclusion order and a cease and desist order.

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) Identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) Indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) Explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3096'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [4]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[5]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.
Issued: November 2, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–28329 Filed 11–5–15; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–970]

Certain Height-Adjustable Desk Platforms and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on October 2, 2015, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Varidesk LLC of Coppell, Texas. A supplement to the complaint was filed on October 26, 2015. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain height-adjustable desk platforms and components thereof by reason of infringement of certain claims of U.S. Patent No. 9,113,703 (''the '703 patent''). The complaint further alleges that an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and a cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2015).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on October 30, 2015, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain height-adjustable desk platforms and components thereof by reason of infringement of one or more of claims 1–4, 6, and 9–11 of the '703 patent, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337;

[4] Handbook for Electronic Filing Procedures: *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf.*

[5] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: Varidesk LLC, 117 Wrangler Drive, Coppell, TX 75019.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served: Brunswick Corp., Life Fitness Division, 1 North Field Court, Lake Forest, IL 60045–4811.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: November 3, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–28328 Filed 11–5–15; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–437 and 731–TA–1060–1061 (Second Review)]

Carbazole Violet Pigment 23 From China and India; Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930, that revocation of the countervailing duty order on carbazole violet pigment 23 from India and revocation of the antidumping duty orders on carbazole violet pigment 23 from China and India would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), instituted these reviews on April 1, 2015 (80 FR 17943) and determined on July 6, 2015 that it would conduct expedited reviews (80 FR 43119, July 21, 2015).

The Commission made these determinations pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on November 2, 2015. The views of the Commission are contained in USITC Publication 4575 (November 2015), entitled *Carbazole Violet Pigment 23 from China and India: Investigation Nos. 701±TA±437 and 731±TA±1060± 1061 (Second Review).*

By order of the Commission.

Issued: November 2, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–28301 Filed 11–5–15; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

DEPARTMENT OF JUSTICE

[OMB Number 1121–0259]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change, of a Previously Approved Collection: Public Safety Officer Medal of Valor

AGENCY: Bureau of Justice Assistance, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Assistance, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until January 5, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments on the estimated burden to facilities covered by the standards to comply with the regulation's reporting requirements, suggestions, or need additional information, please contact Gregory Joy, Program Analyst, Bureau of Justice Assistance, 810 Seventh Street NW., Washington, DC 20531.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Assistance, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether, and if so how, the quality, utility, and clarity of the information to be collected can be enhanced; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Public Safety Officer Medal of Valor (Pub. L. 107–12).

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The application process is managed through the Internet, using the Office of

Justice Programs' (OJP) MOV online application system at: *https://www.bja.gov/programs/medalofvalor/index.html.*

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* The information that is being collected is solicited from federal, state, local and tribal public safety agencies, who wish to nominate their personnel to receive the Public Safety Officer Medal of Valor (MOV). This information is provided on a voluntary basis, includes agency and nominee information along with details about the events for which the nominees are to be considered when determining who will be recommended to receive the MOV.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Over the last four application submission periods, (2011–2012 thru 2014–2015), there were a total of 514 applications received. Taking this number into account, the average number of applications that are anticipated to be received on an annual basis is 128.5. This number does not factor in the ongoing outreach efforts (*e.g.* marketing and social medial outreach) that are intended to increase the number of annual submissions. In addition, it is projected that the application submission process takes approximately 25 minutes. This would include, reviewing the fields of required and optional information, arranging the information and populating the online application form.

6. *An estimate of the total public burden (in hours) associated with the collection:* Based upon the average number of submissions over the last 4 years, and the estimated time required to complete each submission, the estimated annual public burden would be 53.54 hours.

a. 128.5 × 25 minutes = 3,212.5 minutes/60 = 53.54 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: November 3, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–28322 Filed 11–5–15; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Distribution of Characteristics of the Insured Unemployed

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, ''Distribution of Characteristics of the Insured Unemployed,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before December 7, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201506-1205-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Distribution of Characteristics of the Insured Unemployed (Form ETA–203) information collection that provides a once a month snapshot of the demographic composition of the Unemployment Insurance (UI) claimant population. This report is the only source of current and consistent demographic information (age, race/ethnicity, sex, occupation, industry) on the UI claimant population. These characteristics identify important claimant cohorts for legislative, economic and social planning purposes, and evaluation of the UI program on the Federal and State levels. Social Security Act section 303(a)(6) authorizes this information collection. *See* 42 U.S.C. 503(a)(6).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0009.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on December 31, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 13, 2015 (80 FR 27350).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0009. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary

for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: Distribution of Characteristics of the Insured Unemployed.

OMB Control Number: 1205–0009.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 53.

Total Estimated Number of Responses: 636.

Total Estimated Annual Time Burden: 212 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: November 2, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–28312 Filed 11–5–15; 8:45 am]

BILLING CODE 4510–FW–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit modification request.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated under the Antarctic Conservation Act of 1978. This is the required notice of a requested permit modification.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by December 7, 2015. Permit applications may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Division of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, at the above address or *ACApermits@nsf.gov* or (703) 292–7149.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Description of Permit Modification Requested: The Foundation issued a permit (ACA 2015–015) to Joseph A. Covi on December 30, 2014. The issued permit allows the applicant to collect sediment samples in ASPA 132 Potter Peninsula, ASPA 150 Ardley Island, and ASPA 171 Narebski Point, Barton Peninsula, all on King George Island, in order to study the viability and biodiversity of dormant zooplankton, and the presence and origin of anthropogenic chemicals in lakes and ephemeral ponds.

Now the applicant proposes a modification to his permit to add ASPA 125 Fildes Peninsula to the permit, as well as to change the sampling regime and number of samples taken. 1 to 2 lakes would be sampled in each ASPA, with 6 sediment grabs from each lake. Up to 2 ephemeral ponds per ASPA would be sampled, with 3 samples per pond, provided sampling is possible without disturbing the surrounding sediment.

Location: ASPA 125: Fildes Peninsula, King George Island, South Shetland Islands.

Dates: January 6–March 1, 2016.

Nadene G. Kennedy,

Polar Coordination Specialist, Division of Polar Programs.

[FR Doc. 2015–28337 Filed 11–5–15; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL WOMEN'S BUSINESS COUNCIL

Quarterly Public Meeting

AGENCY: National Women's Business Council.

ACTION: Notice of open public meeting.

DATES: The meeting will be held on December 8th, 2015 from 2:00 p.m. to 4:00 p.m. EST.

ADDRESSES: The meeting will take place via teleconference.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), the U.S. Small Business Administration (SBA) announces the meeting of the National Women's Business Council. The National Women's Business Council is tasked with providing policy recommendations on issues of importance and impact to women entrepreneurs to the SBA, Congress, and the White House.

The program will include remarks from the Council Chair, Carla Harris; an update from each of the NWBC committees; and a discussion of the Council's FY2016 agenda. The Council will also preview its FY2015 Annual Report, and introduce the official recommendations—recommendations to improve the business climate for women based on Council's research and engagement from this past year—which will be submitted, as part of the Annual Report, to the SBA, Congress, and the White House later that month.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public, however advance notice of attendance is requested. To RSVP and confirm attendance, the general public should email *info@nwbc.gov* with subject line—''RSVP for 12/8 Public Meeting.'' Anyone wishing to make a presentation to the NWBC at this meeting must either email their interest to *info@nwbc.gov* or call the main office number at 202–205–3850.

For more information, please visit the National Women's Business Council Web site at *www.nwbc.gov.*

Miguel J. L'Heureux,

SBA Committee Management Officer.

[FR Doc. 2015–28348 Filed 11–5–15; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–609; NRC–2013–0235]

Northwest Medical Isotopes, LLC

AGENCY: Nuclear Regulatory Commission.

ACTION: Construction permit application; receipt.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received and is making available the second and final part of a two-part application for a

construction permit, submitted by Northwest Medical Isotopes, LLC (NWMI or the applicant). The applicant proposes to build a medical radioisotope facility located in Columbia, Missouri.

DATES: On July 20, 2015, the applicant filed the second and final part of a two-part application for a construction permit.

ADDRESSES: Please refer to Docket ID NRC–2013–0235 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0235. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Michael F. Balazik, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2856; email: *Michael.Balazik@nrc.gov.*

SUPPLEMENTARY INFORMATION: On July 20, 2015, NWMI filed with the NRC, pursuant to Section 103 of the Atomic Energy Act of 1954, as amended, and part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), the second and final part of a two-part application for a construction permit for a medical radioisotope production facility in Columbia, Missouri (ADAMS Accession No. ML15086A262). The applicant is requesting a combined license in accordance with 10 CFR 50.31 and 10 CFR 50.32.

An exemption from certain requirements of 10 CFR 2.101(a)(5) granted by the Commission on October 7, 2013 (ADAMS Accession No. ML13238A333 and 78 FR 63501), in response to a letter from NWMI dated August 9, 2013 (ADAMS Accession No. ML13227A295), allowed for NWMI to submit its construction permit application in two parts. Specifically, the exemption allowed NWMI to submit a portion of its construction permit application for a construction permit up to six months prior to submitting the remainder of the application regardless of whether or not an environmental impact statement or a supplement to an environmental impact statement is prepared during the review of its application. By letter dated November 7, 2014, NWMI submitted part one of its construction permit application to the NRC. By letter dated February 5, 2015 (ADAMS Accession No. ML15086A262, Package No. ML15086A261), NWMI withdrew and resubmitted part one of its construction permit application and included a discussion of connected actions in its environmental report in response to a January 23, 2015, letter from the NRC (ADAMS Accession No. ML14349A501). A notice of receipt and availability of part one of the construction permit application was previously published in the **Federal Register** on April 21, 2015 (80 FR 22227). The first part of NWMI's construction permit application contained the following information:

• The description and safety assessment of the site required by 10 CFR 50.34(a)(1),

• the environmental report required by 10 CFR 50.30(f),

• the filing fee information required by 10 CFR 50.30(e) and 10 CFR 170.21,

• the general information required by 10 CFR 50.33, and

• the agreement limiting access to classified information required by 10 CFR 50.37.

The NRC staff published in the **Federal Register** on June 8, 2015 (80 FR 32418), its determination that part one of NWMI's construction permit application is acceptable for docketing.

The NWMI states that part two of its application for a construction permit contains the remainder of the preliminary safety analysis report required by 10 CFR 50.34(a).

Subsequent **Federal Register** notices will address the acceptability of this part of the tendered construction permit application for docketing and provisions for public participation in the construction permit application review process.

Dated at Rockville, Maryland, this day 28 of October, 2015.

For the Nuclear Regulatory Commission.

Alexander Adams, Jr.,

Chief, Research and Test Reactors Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–28357 Filed 11–5–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–341; NRC–2014–0109]

DTE Electric Company; Fermi 2 Nuclear Power Plant

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft supplemental environmental impact statement; issuance, public meeting, and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft plant-specific supplement, Supplement 56, to NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants'' (GEIS), regarding the renewal of DTE Electric Company (DTE) operating license NPF–43 for Fermi 2 for an additional 20 years of operation. Possible alternatives to the proposed action (license renewal) include no action and reasonable alternative energy sources. The NRC staff plans to hold one public meeting during the public comment period to present an overview of the draft plant-specific supplements to the GEIS and to accept public comments on the document.

DATES: Submit comments by December 28, 2015. Comments received after this date will be considered, if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0109. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail Comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Elaine Keegan, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 1–800–368–5642, extension 8517; email: *Elaine.Keegan@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2014–0109 when contacting the NRC about the availablitiy of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0109.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The draft plant-specific supplement GEIS is available in ADAMS under Accession No. ML15300A064 for Volume 1 and ML15300A073 for Volume 2.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2014–0109 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comments submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Discussion

The NRC is issuing for public comment the draft plant-specific Supplement 56 to the GEIS for license renewal of nuclear plants, NUREG–1437, regarding the renewal of operating license, NPF–43 for an additional 20 years of operation for Fermi 2. Supplement 56 to the GEIS includes the preliminary analysis that evaluates the environmental impacts of the proposed action and alternatives to the proposed action. The NRC's preliminary recommendation is that the adverse environmental impacts of license renewal for Fermi 2 are not great enough to deny the option of license renewal for energy-planning decisionmakers.

III. Public Meetings

The NRC staff will hold a public meeting prior to the close of the public comment period to present an overview of the draft plant-specific supplement to the GEIS and to accept public comment on the document. The meeting will be held at the Monroe County Community College, La-Z-Boy-Center 1555 S. Raisinville Road, Monroe, Michigan on Wednesday, December 2, 2015. There will be a registration period from 6:30 p.m. until 7:00 p.m. The meeting will start at 7:00 p.m. and continue until 9:00 p.m., as necessary. The meeting will be transcribed and will include: (1) A presentation of the contents of the draft plant-specific supplement to the GEIS; and (2) the opportunity for interested government agencies, organizations, and individuals to provide comments on the draft report. To be considered in the final supplement to the GEIS, comments must be provided either at the transcribed public meeting or submitted in writing by the comment deadline identified in the **DATES** section of this notice. Persons may pre-register to attend or present oral comments at the meeting by contacting Ms. Elaine Keegan, the NRC project manager, at 1–800–368–5642, extension 8517, or by email at *Elaine.Keegan@nrc.gov* no later than Tuesday, November 24, 2015. Members of the public may also register to provide oral comments during the registration period prior to the meeting. Individual oral comments may be limited by the time available, depending on the number of persons who register. If special equipment or accommodations are needed to attend or present information at the public meeting, the need should be brought to Ms. Keegan's attention no later than Tuesday, November 24, 2015, in order to provide the NRC staff with adequate notice to determine whether the request can be accommodated. Additional details regarding the meeting will be posted at least 10 days prior to the public meeting on the NRC's Public Meeting Schedule Web site at *http://www.nrc.gov/public-involve/public-meetings/index.cfm.*

Dated at Rockville, Maryland, this 29 day of October 2015.

For the Nuclear Regulatory Commission.

James G. Danna,

Chief, Projects Branch 2, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–28265 Filed 11–5–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–338 and 50–339; NRC–2012–0258; License Nos.: NPF–4 and NPF–7]

North Anna Power Station, Units 1 and 2, Virginia Electric and Power Company

AGENCY: Nuclear Regulatory Commission.

ACTION: Revised director's decision under 10 CFR 2.206; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is giving notice that the Director of the Office of Nuclear Reactor Regulation has issued a revised final Director's Decision (DD) with regard to a petition dated October 20, 2011, filed by Paul Gunter et al., herein referred to as ''the petitioners.''

DATES: November 6, 2015.

ADDRESSES: Please refer to Docket ID NRC–2012–0258 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0258. Address questions about NRC dockets to Carol

Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: V. Sreenivas, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2597; email: *V.Sreenivas@nrc.gov.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Director of the Office of Nuclear Reactor Regulation, has issued a revision to a Director's Decision (DD) dated August 21, 2015 (ADAMS Accession No. 15175A465), with regard to a petition dated October 20, 2011 (ADAMS Accession No. ML11293A116), filed by the petitioners. The petition was supplemented on November 2, 2011 (ADAMS Accession No. ML11308A027) and December 15, 2011 (ADAMS Accession No. ML12060A197). The petition concerns the operation of the North Anna Power Station, Units 1 and 2 (North Anna 1 and 2), by the Virginia Electric and Power Company (VEPCO or the licensee). The petition requested that the NRC suspend the operating licenses for North Anna 1 and 2, until the completion of a set of activities described in the petition. The petitioner also requested that a public meeting be held to discuss this matter in the Washington, DC area.

As the basis for the October 20, 2011, request, the petitioner raised several concerns, of which 12 were accepted for review by the NRC staff by letter dated March 16, 2012 (ADAMS Accession No. ML12060A090). These are summarized as follows:

(1) Prior to the approval of restart for North Anna 1 and 2, after the earthquake of August 23, 2011, VEPCO should be required to obtain a license amendment from the NRC that reanalyzes and reevaluates the plant's design basis for earthquakes and for associated necessary retrofits.

(2) Prior to the approval of restart for North Anna 1 and 2, after the earthquake of August 23, 2011, the licensee should be required to ensure that North Anna 1 and 2, are subjected to thorough inspections of the same level and rigor.

(3) The licensee should be required to reanalyze and reevaluate the North Anna Independent Spent Fuel Storage Installation (lSFSI) due to damage caused by the earthquake of August 23, 2011, and ensure that no threat is posed to public health and safety by its operation.

(4) The licensee should ensure the reliability and accuracy of the seismic instrumentation at North Anna 1 and 2.

(5) The NRC staff made hasty decisions about the restart of North Anna 1 and 2, and gave priority to economic considerations. The long-term action plan was not even complete before the NRC staff gave authorization to restart.

(6) Regulatory commitments are an inadequate regulatory tool for ensuring that the critical long-term tasks identified in the NRC staff's confirmatory action letter dated November 11, 2011, are completed.

(7) The licensee needs to address the possibility of both boildown and rapid draindown events at the North Anna 1 and 2, spent fuel pool (SFP).

(8) The long-term storage of spent fuel in the SFP at North Anna 1 and 2, and at the North Anna ISFSI poses challenges to the public health and safety.

(9) ''Hardened on-site storage'' strategies for spent fuel should be used at North Anna 1 and 2.

(10) Concerns exist about the response of North Anna 1 and 2, to a prolonged station blackout.

(11) The current emergency evacuation plans for North Anna 1 and 2, need to be revised to reflect the possible need to evacuate a larger area than that identified in the current emergency planning zone.

(12) Concerns exist about damage to the structural integrity of the spent fuel pool structure at North Anna 1 and 2, as represented on pages 41 and 42 of the NRC staff's technical evaluation for the restart of North Anna 1 and 2, dated November 11, 2011.

On December 12, 2012 and February 2, 2012, the petitioners and the licensee met with the NRC staff's petition review board (meeting transcripts under ADAMS Accession Nos. ML12033A025 and ML12047A240), regarding the petition. These meetings gave the petitioner and the licensee an opportunity to provide additional information and to clarify issues raised in the petition.

The NRC staff issued a partial DD on October 19, 2012 (ADAMS Accession No. ML12262A156). Twelve of the concerns were accepted for review by the NRC staff. As detailed in the partial DD, eight of these concerns were closed. The remaining four concerns accepted for review were identified as those that may take longer than the target timeframe for reaching a decision on a petition based on the fact they were undergoing NRC review as part of the agency's response to the Fukushima event in Japan.

Regarding the four remaining concerns, the NRC staff sent a copy of the proposed DD to the Petitioners and to the licensee for comment on April 17, 2015 (ADAMS Accession Nos. ML14311A616 and ML15061A133, respectively). The Petitioners provided comments in a response dated May 18, 2015 (ADAMS Accession No. ML15138A277) and the licensee provided comments in a response dated May 20, 2015 (ADAMS Accession No. ML15147A517). The comments and the NRC staff's response to them are included with this director's decision.

On August 21, 2015, the NRC issued a director's decision (ADAMS Accession No. ML15175A465). Subsequently, the NRC identified portions of the director's decision on the long-term storage of spent fuel in the SFP and ISFSI that required clarification. Accordingly, the decision's response to Concern 8 is revised to clarify the NRC's resolution of the concern.

The Director of the Office of Nuclear Reactor Regulation has determined that the request to suspend the operating licenses for North Anna 1 and 2, until the completion of a set of activities described in the petition, be partially granted and partially denied. The reasons for this decision are explained in the revised director's decision DD–15–09 pursuant to section 2.206 of title 10 of the *Code of Federal Regulations* (10 CFR) of the Commission's regulations.

The NRC will file a copy of the revised director's decision with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206. As provided for by this regulation, the director's decision will constitute the final action of the Commission 25 days after the date of the

decision, unless the Commission, on its own motion, institutes a review of the director's decision in that time.

Dated at Rockville, Maryland, this 30th day of October, 2015.

For the Nuclear Regulatory Commission.

William M. Dean,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–28361 Filed 11–5–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0001]

Sunshine Act Meeting Notice

DATES: November 9, 16, 23, 30, December 7, 14, 2015.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of November 9, 2015

Monday, November 9, 2015

2:45 p.m. Affirmation Session (Public Meeting) (Tentative).

a. *Pacific Gas and Electric Company* (Diablo Canyon Nuclear Power Plant), *Friends of the Earth's Appeal of LBP±15±6* (Tentative)

b. *Entergy Nuclear Operations, Inc.* (Palisades Nuclear Plant)—Appeal of LBP–15–17 (Tentative)

c. *Entergy Nuclear Operations, Inc.* (Palisades Nuclear Plant)—Appeal of LBP–15–20 (Tentative)

d. *Entergy Nuclear Operations, Inc.* (Indian Point Nuclear Generating Units 2 and 3)—Petition for Interlocutory Review of Atomic Safety and Licensing Board's July 20, 2015 Order (Denying New York Motion to Withdraw Proprietary Designation) (Tentative).

Week of November 16, 2015—Tentative

Tuesday, November 17, 2015

9:00 a.m. Briefing on the Status of Lessons Learned from the Fukushima Dai-Ichi Accident (Public Meeting); (Contact: Gregory Bowman: 301–415–2939).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, November 19, 2015

9:00 a.m. Hearing on Combined Licenses for South Texas Project, Units 3 and 4: Section 189a of the Atomic Energy Act Proceeding (Public Meeting); (Contact: Tom Tai: 301–415–8484).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of November 23, 2015—Tentative

There are no meetings scheduled for the week of November 23, 2015.

Week of November 30, 2015—Tentative

Thursday, December 3, 2015

9:30 a.m. Briefing on Equal Employment Opportunity and Civil Rights Outreach (Public Meeting); (Contact: Larniece McKoy Moore: 301–415–1942).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of December 7, 2015—Tentative

There are no meetings scheduled for the week of December 7, 2015.

Week of December 14, 2015—Tentative

Tuesday, December 15, 2015

9:00 a.m. Hearing on Construction Permit for SHINE Medical Isotope Production Facility: Section 189a of the Atomic Energy Act Proceeding (Public Meeting); (Contact: Steven Lynch: 301–415–1524).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, December 17, 2015

9:30 a.m. Briefing on Project AIM 2020 (Public Meeting); (Contact: John Jolicoeur 301–415–1642).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

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The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

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The NRC Commission Meeting Schedule can be found on the Internet at:*http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: November 4, 2015.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2015–28482 Filed 11–4–15; 4:15 pm]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76327; File No. SR–BATS–2015–93

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Delete Rule 22.10, Limitations on Dealings

November 2, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 21, 2015, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6)(iii) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal for the BATS Options Market (''BATS Options'') to adopt a principles-based approach to prohibit the misuse of material nonpublic information by Market Makers by deleting Rule 22.10 (Limitations on Dealings).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6)(iii).

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt a principles-based approach to prohibit the misuse of material non-public information by Market Makers by deleting Rule 22.10 (Limitations on Dealings). In doing so, the Exchange, with regard to BATS Options, would harmonize its rules governing Market Makers and Options Members that are not Market Makers relating to the protection against misuse of material, non-public information. The Exchange believes that Rule 22.10 is no longer necessary because all Options Members, including Market Makers, are subject to the Exchange's generally applicable principles-based requirements governing the protection against the misuse of material, non-public information, pursuant to Rule 5.5 (Prevention of the Misuse of Material, Non-Public Information), which obviates the need for separately prescribed requirements for a subset of Exchange participants. Additionally, there is no separate regulatory purpose served by having separate rules for Market Makers. The Exchange notes that this proposed rule change will not decrease the protections against the misuse of material, non-public information; instead, it is designed to provide more flexibility to Options Members. This is a competitive filing that is based on a proposal recently submitted by NYSE MKT LLC (''NYSE MKT'') and approved by the Commission.[5]

Background

The Exchange has two classes of BATS Options participants. Specifically, pursuant to Rule 16.1.(a)(38), the term ''Options Member'' means a firm or organization that is registered with the Exchange pursuant to Chapter XVII of the Rules for the purposes of participating in options trading on BATS Options either as an ''Options Order Entry Firm'' or as an ''Options Market Maker.'' Pursuant to Rule 16.1(a)(36), the terms ''Options Order Entry Firm'' or ''Order Entry Firm'' or ''OEF'' mean those Options Members representing as agent Customer Orders on BATS Options and those non-Market Maker Members conducting proprietary trading. Pursuant to Rule 16.1(a)(37), the term ''Options Market Maker'' or ''Market Maker'' means an Options Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter XXII of the Rules.

Rule 22.5 (Obligations of Market Makers) describes the obligations of Market Makers. Rule 22.6 (Market Maker Quotations) sets forth quoting obligations of Market Makers.[6] Rule 22.10 (Limitations on Dealings) requires Market Makers to maintain information barriers that are reasonably designed to prevent the misuse of material, non-public corporate or markets information in the possession of persons on one side of the information barrier by persons on the other side of the information barrier.

Proposed Rule Change

The Exchange believes that the particularized guidelines for Market Makers in Rule 22.10 are no longer necessary and proposes to delete Rule 22.10. The Exchange believes that Rule 5.5 (Prevention of the Misuse of Material, Nonpublic Information), which governs the misuse of material, non-public information and applies to all Members (including Options Members), provides an appropriate, principles-based approach to prevent the market abuses that Rule 22.10 seeks to address. Specifically, Rule 5.5 requires every Member (including Options Members) to establish, maintain, and enforce written policies and procedures reasonably designed to prevent the misuse of material, non-public information by such Member or persons associated with such Member. For purposes of Rule 5.5, the misuse of material, non-public information includes, but is not limited to, the following:

(1) Trading in any securities issued by a corporation, or in any related securities or related options or other derivative securities, while in possession of material, non-public information concerning that issuer;

(2) Trading in a security or related options or other derivative securities, while in possession of material, non-public information concerning imminent transactions in the security or related securities; and

(3) Disclosing to another person or entity any material nonpublic information involving a corporation whose shares are publicly traded or an imminent transaction in an underlying security or related securities for the purpose of facilitating the possible misuse of such material nonpublic information.

Because Options Members are already subject to the requirements of Rule 5.5, the Exchange does not believe that it is necessary to separately require particularized limitations on Market Makers. Deleting Rule 22.10, with its particularized limitations would provide Market Makers with the flexibility to adapt their policies and procedures as appropriate to reflect changes to their business model, business activities, or the securities market in a manner similar to how Options Members on the Exchange currently operate in conformity with Rule 5.5.

As noted above, Market Makers are distinguished under Exchange rules from other Options Members only to the extent that Market Makers have heightened quoting obligations. However, such heightened quoting obligations do not afford different or greater access to nonpublic information than any other Options Member of the Exchange.[7] Therefore, because Market Makers do not have any trading advantages over Order Entry Firms on BATS Options, the Exchange believes

[5] *See* Securities Exchange Act Release No. 75432 (July 13, 2015), 80 FR 42597 (July 17, 2015) (Order Approving SR–NYSEMKT–2015–23).

[6] Rule 22.6 generally requires that Market Makers provide firm, two-sided, continuous quotations, in minimum size, for the options series to which it is registered.

[7] The Exchange notes that by deleting Rule 22.10, the Exchange would no longer require specific information barriers for Market Makers; however, as is the case currently with Options Members, information barriers of new participants would be subject to review as part of a new firm application. Moreover, the policies and procedures of Market Makers, including those relating to any information barriers, would be subject to review by FINRA, on behalf of the Exchange, pursuant to a Regulatory Services Agreement.

that they should be subject to the same rules regarding the protection against the misuse of material non-public information, which in this case, is existing Rule 5.5.

The Exchange notes that its proposed approach to use a principles-based approach to protecting against the misuse of material non-public information for all of its registered Options Members is consistent with recently approved rule changes for NYSE MKT and recently filed changes for the International Securities Exchange LLC (''ISE'') and the Boston Options Exchange LLC (''BOX'').[8] Each of these exchanges has moved to a principles-based approach to protecting against the misuse of material non-public information. In connection with approving those rule changes, the Commission found that, with adequate oversight by the exchanges of their members, eliminating prescriptive information barrier requirements should not reduce the effectiveness of exchange rules requiring its members to establish and maintain systems to supervise the activities of its members, including written procedures reasonably designed to ensure compliance with applicable federal securities law and regulations, and with the rules of the applicable exchange.[9]

The Exchange believes that a principles-based rule applicable to members of options markets would be effective in protecting against the misuse of material non-public information. Indeed, Exchange Rule 5.5 is currently applicable to Options Members and already requires policies and procedures reasonably designed to prevent the misuse of material nonpublic information. The Exchange believes that Rule 5.5 provides appropriate protection against the misuse of material nonpublic information by Options Members and that there is no longer a need for prescriptive information barrier requirements set forth in Rule 22.10.

The Exchange notes that even with this proposed rule change and the elimination of the requirement that the Exchange pre-approve a Member's policies and procedures, pursuant to Rule 5.5, an Options Member would still be obligated to ensure that its policies and procedures reflect the current state of its business and continue to be reasonably designed to achieve compliance with applicable federal securities law and regulations, including Section 15(g) of the Act,[10] and with applicable Exchange rules, including being reasonably designed to protect against the misuse of material, non-public information. Thus, the Exchange does not believe there will be any material change to Member's information barriers as a result of the Exchange's pre-approval no longer being required. In fact, the Exchange anticipates that the lack of such pre-approval would facilitate Market Maker's ability to more quickly implement changes to their information barrier as necessary to protect against the misuse of material, non-public information.

The Exchange is not proposing to change what is considered to be material, non-public information and, thus, would not expect there to be any changes to the types of information that an affiliated brokerage business of a Market Maker could share with such Market Maker. In addition, the Exchange notes that the proposed rule change would not permit the affiliates of a Market Maker to have access to any non-public order or quote information of the Market Maker, including the non-displayed size of Reserve Orders.[11] Affiliates of Market Makers would only be permitted to have access to orders and quotes that are publicly available to all market participants.

While information barriers would not specifically be required under the proposal, Rule 5.5 already requires that an Options Member consider its business model or business activities in structuring its policies and procedures, which may dictate that an information barrier or a functional separation be part of the appropriate set of policies and procedures that would be reasonably designed to achieve compliance with applicable securities law and regulations, and with applicable Exchange rules.

The Exchange believes that the proposed reliance on the principles-based Rule 5.5 would ensure that an Options Member would be required to protect against the misuse of any material non-public information. As noted above, Rule 5.5 already requires that Members refrain from trading while in possession of material non-public information concerning imminent transactions in the security or related product. The Exchange believes that moving to a principles-based approach rather than prescribing particularized information barriers applicable to Market Makers would provide Market Makers with flexibility when managing risk across a firm, including integrating options positions with other positions of the firm or, as applicable, by the respective independent trading unit.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[12] In particular, the proposal is consistent with Section 6(b)(5) of the Act [13] because it is designed to prevent fraudulent and manipulative acts and practices, would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general protect investors and the public interest.

The Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market by adopting a principles-based approach to permit an Options Member to maintain and enforce policies and procedures to, among other things, prohibit the misuse of material non-public information and provide flexibility on how a Market Maker structures its operations. The Exchange notes that the proposed rule change is based upon an approved rule of the Exchange to which Options Members are subject—Rule 5.5—and the proposed change harmonizes the rules governing Options Members. Moreover, Market Makers would continue to be subject to federal and Exchange requirements for protecting material non- public order information.[14] The Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market because it would harmonize the Exchange's approach to protecting against the misuse of material

[8] *See* Securities Exchange Act Release No. 75432 (July 13, 2015), 80 FR 42597 (July 17, 2015) (Order Approving Adopting a Principles-Based Approach to Prohibit the Misuse of Material Nonpublic Information by Specialists and e-Specialists by Deleting Rule 927.3NY and Section (f) of Rule 927.5NY). *See also* Securities Exchange Act Release Nos. 75792 (August 31, 2015), 80 FR 53601 (September 4, 2015) (SR–ISE–2015–26) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Adopting a Principles-Based Approach To Prohibit the Misuse of Material, Non-Public Information by Market Makers by Deleting Rule 810); 75916 (September 14, 2015), 80 FR 56503 (September 18, 2015) (SR–BOX–2015–31) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a Principles-Based Approach To Prohibit the Misuse of Material Nonpublic Information by Market Makers).

[9] *See* supra note 8.

[10] 15 U.S.C 78o(g).

[11] Reserve Orders are described in Rule 21.1(d) and include both a quantity that is displayed and a reserve portion that is not displayed.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *See* 15 U.S.C. 78o(g) and Rule 5.5.

nonpublic information and no longer subject Market Makers to particularized prescriptive requirements. The Exchange does not believe that the existing prescriptive requirements applicable to Options Market Makers are narrowly tailored to their respective role because Market Makers do not have access to Exchange trading information in a manner different from any other Options Member that is not a Market Maker.

The Exchange further believes the proposal is designed to prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade because existing rules make clear to Options Members the type of conduct that is prohibited by the Exchange. While the proposal eliminates certain prescriptive requirements relating to the misuse of material non-public information, Market Makers would remain subject to existing Exchange rules requiring them to establish and maintain systems to supervise their activities, and to create, implement, and maintain written procedures that are reasonably designed to comply with applicable securities laws and Exchange rules, including the prohibition on the misuse of material, nonpublic information. Additionally, the policies and procedures of Market Makers, including those relating to information barriers, would be subject to review by FINRA, on behalf of the Exchange.[15]

The Exchange notes that the proposed rule change would still require that Market Makers maintain and enforce policies and procedures reasonably designed to ensure compliance with applicable federal securities laws and regulations and with Exchange rules. Even though there would no longer be particularized Market Maker information barriers, any Market Maker written policies and procedures would continue to be subject to oversight by the Exchange and therefore the elimination of prescribed requirements should not reduce the effectiveness of the Exchange rules to protect against the misuse of material non-public information. Rather, all Options Members will be able to utilize a flexible, principles-based approach to modify their policies and procedures as appropriate to reflect changes to their business model, business activities, or to the securities market itself. Moreover, while particularized information barriers may no longer be required, an Options Member's business model or business activities may dictate that an information barrier or functional separation be part of the appropriate set of policies and procedures that would be reasonably designed to achieve compliance with applicable securities laws and regulations, and with applicable Exchange rules. The Exchange therefore believes that the proposed rule change will maintain the existing protection of investors and the public interest that is currently applicable to Market Makers, while at the same time removing impediments to and perfecting a free and open market by moving to a principles-based approach to protect against the misuse of material non-public information.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to a filing submitted by NYSE MKT that was recently approved by the Commission.[16] The Exchange believes this proposed rule change is necessary to permit fair competition among the options exchanges.

The Exchange believes that the proposal will enhance competition by allowing Market Makers to comply with applicable Exchange rules in a manner best suited to their business models, business activities, and the securities markets, thus reducing regulatory burdens while still ensuring compliance with applicable securities laws and regulations and Exchange rules. The Exchange believes that the proposal will foster a fair and orderly marketplace without being overly burdensome upon Market Makers.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (A) Significantly affect the protection of investors or the public interest; (B) impose any significant burden on competition; and (C) by its terms, become operative for 30 days from the date on which it was filed or such shorter time as the Commission may designate it has become effective pursuant to Section 19(b)(3)(A) of the Act[17] and paragraph (f)(6) of Rule 19b–4 thereunder,[18] the Exchange has designated this rule filing as non-controversial. The Exchange has given the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (1) Necessary or appropriate in the public interest; (2) for the protection of investors; or (3) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BATS–2015–93 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BATS–2015–93. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule

[15] *See supra,* note 7.

[16] *See supra,* note 5.

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4.

change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BATS–2015–93 and should be submitted on or before November 27, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2015–28268 Filed 11–5–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76326; File No. SR–CHX–2015–08]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Its Smart Versus Direct Routing Protocol

November 2, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on October 26, 2015, the Chicago Stock Exchange, Inc. (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CHX proposes to modify its smart versus direct order routing protocol. CHX has designated this proposed rule change as non-controversial pursuant to Section 19(b)(3)(A)[3] of the Act and Rule 19b–4(f)(6)[4] thereunder and has provided the Commission with the notice required by Rule 19b–4(f)(6)(iii).[5] The text of this proposed rule change is available on the Exchange's Web site at (*www.chx.com*) and in the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify its smart versus direct order routing protocol, which was recently clarified and modified under SR–CHX–2015–02.[6] Specifically, the Exchange proposes to (1) eliminate the Exchange's special routing handling for Protected Quotations[7] displayed on the Alternative Display Facility (''ADF'') operated by the Financial Industry Regulatory Authority (''FINRA'')[8] (''ADF special handling'')[9] and (2) to always direct a non-affiliate third-party routing broker (''third-party routing broker'') to route orders to specific routing destinations, when required by CHX Rules,[10] including situations where orders would be routed pursuant to a routing table maintained by the Exchange, as described in detail below. The Exchange does not propose to substantively modify the smart versus direct order routing protocol or the CHX Routing Services in any other way.

Currently, upon the triggering of a Routing Event,[11] the Exchange will route away Routable Orders,[12] or portions thereof, through CHXBD, LLC, which is an affiliated routing broker that operates as a facility of the Exchange, which would then forward orders to a third-party routing broker for routing to the ultimate routing destination.[13] All orders routed to the third-party routing broker will include instructions for the third-party routing broker to either direct route the order to a specific destination or to smart route the order utilizing the third-party routing broker's routing technology, pursuant to a routing table provided and maintained by the Exchange. The decision to smart or direct route orders is made by the Exchange pursuant to the following smart versus direct order routing protocol:[14]

- Smart route. Subject to ADF special handling, if the portion of a Routable Order that is to be routed away at a certain price point is smaller than the aggregate size of two or more contra-side Protected Quotations that could be satisfied at that price point, the Exchange will rely on a third-party routing broker to utilize its smart routing technology to route away the corresponding orders pursuant to a routing table provided by the Exchange. When orders are smart routed, the relevant snapshot of Protected Quotations of external markets for Regulation NMS purposes will be taken by the third-party routing broker and the third-party routing broker would route orders marked Immediate Or Cancel[15] and Intermarket Sweep Order[16] (''IOC/ISO'').
- Direct route. Subject to ADF special handling, if the portion of a Routable Order that is to be routed away at a certain price point is smaller than the size of one contra-side Protected Quotation that could be satisfied or is the same size as the aggregate size of one or more contra-side Protected Quotations that could be satisfied at that price point, the Exchange will direct the third-party routing broker to route corresponding orders to specific routing destinations. Thus, the relevant snapshot of the Protected Quotations of

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] 17 CFR 240.19b–4(f)(6)(iii).

[6] *See* Exchange Act Release No. 74487 (March 12, 2015), 80 FR 14193 (March 18, 2015) (SR–CHX–2015–02).

[7] *See* 17 CFR 242.600(a)(58).

[8] *See* FINRA Rule 6210.

[9] *See supra* note 6.

[10] *See* CHX Article 19, Rule 3(a).

[11] *Id.*

[12] *See* CHX Article 1, Rule 1(oo).

[13] *See* Exchange Act Release No. 73150 (September 19, 2014), 79 FR 57603 (September 25, 2014) (SR–CHX–2014–15).

[14] *See supra* notes 6 and 13.

[15] *See* CHX Article 1, Rule 2(d)(4).

[16] *See* CHX Article 1, Rule 2(b)(3)(B).

external markets for Regulation NMS purposes will be taken by the Exchange and the Exchange would route IOC/ISOs to the third-party routing broker along with instructions to route the orders to a specific destination.

• ADF Special Handling. If one of the contra-side Protected Quotations described above is displayed on the ADF, the Exchange will route the entire remaining balance of the Routable Order to a third-party routing broker for smart routing.

The Exchange now proposes to always direct a third-party routing broker to route orders to specific routing destinations, regardless of whether an order would be smart or direct routed. Specifically, if the Exchange's routing systems determine that a Routable Order should be smart routed, the Exchange's routing systems will create the necessary corresponding orders (as opposed to handing such responsibilities to the third-party routing broker), pursuant to a routing table maintained by the Exchange, and direct the third-party routing broker to route the corresponding orders to specific routing destinations. Thus, the result is that the Exchange will *always* direct a third-party routing broker to route IOC/ISOs to specific destinations. Also, the Exchange proposes to eliminate ADF special handling and treat Protected Quotations displayed on the ADF like any other Protected Quotations displayed in the national market system. Thus, the smart versus direct order routing protocol would be simplified as follows:

• Smart route. If the portion of a Routable Order that is to be routed away at a certain price point is smaller than the aggregate size of two or more contra-side Protected Quotations that could be satisfied at that price point, the Exchange will utilize its smart routing technology and direct the third-party routing broker to route IOC/ISO(s) to specific routing destinations.

• Direct route. If the portion of a Routable Order that is to be routed away is smaller than the size of one contra-side Protected Quotation that could be satisfied or is the same size as the aggregate size of one or more contra-side Protected Quotations that could be satisfied at that price point, the Exchange will direct the third-party routing broker to route IOC/ISO(s) to specific routing destinations.

• In either scenario, the relevant snapshot of Protected Quotations of external markets will be taken by the Exchange.

Operative Date

The Exchange proposes to make the proposed rule change operative as follows:

• The proposal for the Exchange to always direct a third-party routing broker to route orders to specific destinations shall be operative *October 29, 2015,* prior to the Exchange's Regulation SCI compliance date of November 3, 2015.[17]

• The proposed elimination of ADF special handling shall be operative pursuant to two weeks' notice by the Exchange to its Participants via Information Memorandum on a date to coincide with the operative date of CHX Sub-second Non-displayed Auction Process (''SNAP''),[18] which will not occur during the thirty (30) day pre-operative waiting period contained in Exchange Act Rule 19b–4(f)(6)(iii).[19]

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act in general [20] and furthers the objectives of Section 6(b)(5) in particular,[21] in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments and perfect the mechanisms of a free and open market, and, in general, to protect investors and the public interest. Specifically, the Exchange believes that the proposal removes impediments and perfects the mechanisms of a free and open market by streamlining the CHX Routing Services through simplifying the smart versus direct routing protocol, which also protects investors and the public interest.

B. Self-Regulatory Organization's Statement of Burden on Competition

The Exchange does not believe that the proposal will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that the proposal will enhance competition by streamlining the CHX Routing Services. Thus, the proposal is a competitive proposal that is intended to draw additional order flow to the Exchange, which will, in turn, benefit the Exchange and all Participants.

C. Self-Regulatory Organization's Statement on Comments Regarding the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [22] and Rule 19b–4(f)(6) thereunder.[23]

The Exchange has requested that the Commission waive the requirement that the rule change not become operative for 30 days after the date of the filing as set forth in Rule 19b–4(f)(6)(iii),[24] so that the proposal may become immediately operative upon filing. The Exchange has stated that it desires to operate under the proposal to begin always directing a third-party routing broker to route orders to specific destinations on October 29, 2015, allowing the proposal to be fully implemented prior to the Exchange's Regulation SCI compliance date of November 3, 2015.[25] Waiver of the operative waiting period and implementation prior to the SCI compliance date would permit the Exchange to exclude the third-party routing broker from its Regulation SCI compliance responsibilities. In addition, the Exchange believes that an operative date ahead of the Exchange's actual Regulation SCI compliance date is necessary to better ensure that the proposed modification is operating properly before the Exchange's Regulation SCI compliance date. For those reasons, the Commission finds that waiver of the 30-day pre-operative waiting period is consistent with the protection of investors and the public. The Commission hereby waives the 30-

[17] *See* Exchange Act Release No. 73639 (December 5, 2014), 79 FR 72251 (December 5, 2014).

[18] The proposed rule change to adopt SNAP was recently approved, but is not yet operative. *See* Securities Exchange Act Release No. 76087 (October 6, 2015), 80 FR 61540 (October 13, 2015).

[19] *Id.*

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), CHX provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[24] 17 CFR 240.19b–4(f)(6)(iii).

[25] *See supra* note 17.

day operative delay and designates the proposal effective upon filing.[26]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CHX–2015–08 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CHX–2015–08. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090. Copies of the filing will also be available for inspection and copying at the Exchange's principal office. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CHX–2015–08 and should be submitted on or before November 27, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2015–28267 Filed 11–5–15; 8:45 am]

BILLING CODE 8011–01–P

[26] For purposes of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of CodeSmart Holdings, Inc.; Order of Suspension of Trading

November 4, 2015

It appears to the Securities and Exchange Commission (''Commission'') that there is a lack of current and accurate information concerning the securities of CodeSmart Holdings, Inc. (''CodeSmart'') because it has not filed any periodic reports since the period ended June 30, 2014 and that suspicious market activity involving securities of CodeSmart has taken place. CodeSmart is a Florida corporation with its principal place of business in Mohnton, Pennsylvania. Its stock is quoted on OTC Link, operated by OTC Markets Group Inc., under the ticker: ITEN. The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of CodeSmart.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EST on November 4, 2015, through 11:59 p.m. EST on November 17, 2015.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2015–28413 Filed 11–4–15; 11:15 am]

BILLING CODE 8011–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: August 1–31, 2015.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(f) for the time period specified above:

Approvals by Rule Issued Under 18 CFR 806.22(f)

1. EOG Resources, Inc., Pad ID: PHC 7H, ABR–20090722.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 1.9999 mgd; Approval Date: August 6, 2015.
2. Chevron Appalachia, LLC, Pad ID: Hutton Unit #1H, ABR–20090518.R1, Chest Township, Clearfield County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: August 11, 2015.
3. Chevron Appalachia, LLC, Pad ID: Lytle Unit Drilling Pad #1H, ABR–20100104.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: August 11, 2015.
4. Chevron Appalachia, LLC, Pad ID: Shannon Land & Mining Drilling Pad #1, ABR–20100628.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: August 11, 2015.
5. Chevron Appalachia, LLC, Pad ID: Snow Shoe 2, ABR–201011007.R1, Snow Shoe Township, Centre County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 11, 2015.
6. Chevron Appalachia, LLC, Pad ID: Snow Shoe 4, ABR–201011042.R1,

Snow Shoe Township, Centre County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 11, 2015.

7. Chevron Appalachia, LLC, Pad ID: Smithmyer Drilling Pad #1, ABR–201101020.R1, Clearfield Township, Cambria County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: August 11, 2015.
8. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 285 Pad G, ABR–201007002.R1, Grugan Township, Clinton County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 13, 2015.
9. Anadarko E&P Onshore, LLC, Pad ID: Robert C Ulmer Pad A, ABR–201007049.R1, Watson Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 13, 2015.
10. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 343 Pad B, ABR–201007053.R1, Beech Creek Township, Clinton County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 13, 2015.
11. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 285 Pad C, ABR–201007062.R1, Grugan Township, Clinton County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 13, 2015.
12. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 290 Pad B, ABR–201008029.R1, McHenry Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 13, 2015.
13. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 289 Pad D, ABR–201008030.R1, McHenry Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 13, 2015.
14. EOG Resources, Inc., Pad ID: COP Pad C, ABR–201008027.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: August 14, 2015.
15. EOG Resources, Inc., Pad ID: COP Pad J, ABR–201009022.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: August 14, 2015.
16. EOG Resources, Inc., Pad ID: COP Pad N, ABR–201103001.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: August 14, 2015.
17. EOG Resources, Inc., Pad ID: COP Pad O, ABR–201103030.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: August 14, 2015.
18. Chief Oil & Gas, LLC, Pad ID: Curtin Drilling Pad #1, ABR–201012034.R1, Albany Township, Bradford County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: August 14, 2015.
19. SWEPI LP, Pad ID: Barbine 292, ABR–20100614.R1, Charleston Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 14, 2015.
20. SWEPI LP, Pad ID: Erickson 423, ABR–20100618.R1, Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 14, 2015.
21. SWEPI LP, Pad ID: Hege 426, ABR–20100622.R1, Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 14, 2015.
22. SWEPI LP, Pad ID: Allen 620, ABR–20100623.R1, Charleston Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 14, 2015.
23. SWEPI LP, Pad ID: Hazelton 424, ABR–20100626.R1, Shippen Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 14, 2015.
24. SWEPI LP, Pad ID: Pierson 810, ABR–20100633.R1, Gains Township, Tioga County, Pa.; Consumptive Use of Up to 4.9900 mgd; Approval Date: August 14, 2015.
25. SWEPI LP, Pad ID: Doan 893, ABR–20100670.R1, Deerfield Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 14, 2015.
26. Cabot Oil & Gas Corporation, Pad ID: KingD P1, ABR–201009010.R1, Dimock Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.5750 mgd; Approval Date: August 14, 2015.
27. Cabot Oil & Gas Corporation, Pad ID: CosnerW P1, ABR–201009047.R1, Springville Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.5750 mgd; Approval Date: August 14, 2015.
28. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 356 Pad D, ABR–201007052.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
29. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 357 Pad B, ABR–201007072.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
30. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 356 Pad A, ABR–201007073.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
31. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 285 Pad E, ABR–201007074.R1, Grugan Township, Clinton County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 14, 2015.
32. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 357 Pad A, ABR–201007075.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
33. Anadarko E&P Onshore, LLC, Pad ID: Clearview HC Pad A, ABR–201007076.R1, Gamble Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
34. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 356 Pad I, ABR–201007114.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
35. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 356 Pad F, ABR–201007124.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
36. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 285 Pad F, ABR–201008007.R1, Chapman Township, Clinton County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
37. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 285 Pad D, ABR–201008013.R1, Chapman Township, Clinton County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
38. Anadarko E&P Onshore, LLC, Pad ID: Charles J McNamee Pad B, ABR–201008016.R1, Cascade Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.

39. Anadarko E&P Onshore, LLC, Pad ID: Elbow Pad C, ABR–201008017.R1, Cogan House Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
40. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 285 Pad H, ABR–201008018.R1, Chapman Township, Clinton County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
41. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 344 Pad B, ABR–201008019.R1, Grugan Township, Clinton County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
42. Anadarko E&P Onshore, LLC, Pad ID: COP Tr 356 Pad H, ABR–201008020.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
43. Anadarko E&P Onshore, LLC, Pad ID: Elbow Pad A, ABR–201008055.R1, Cogan House Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
44. Anadarko E&P Onshore, LLC, Pad ID: Brian K Frymire Pad A, ABR–201008056.R1, Cascade Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 14, 2015.
45. Anadarko E&P Onshore, LLC, Pad ID: Ann M. Mercier Pad A, ABR–201007071.R1, Cogan House Township, Lycoming County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 18, 2015.
46. SWEPI LP, Pad ID: Shelman 291, ABR–20100659.R1, Charleston Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 18, 2015.
47. SWEPI LP, Pad ID: Hauswirth 516, ABR–20100688.R1, Richmond Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 18, 2015.
48. SWEPI LP, Pad ID: Martin 806, ABR–20100691.R1, Gaines Township, Tioga County, Pa.; Consumptive Use of Up to 4.9900 mgd; Approval Date: August 18, 2015.
49. Talisman Energy USA Inc., Pad ID: Roy 03 046, ABR–20100629.R1, Wells Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
50. Talisman Energy USA Inc., Pad ID: Roy 03 040, ABR–20100650.R1, Wells Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
51. Talisman Energy USA Inc., Pad ID: Shedden 01 075, ABR–201007004.R1, Granville Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
52. Talisman Energy USA Inc., Pad ID: Noble 03 029, ABR–201007011.R1, Wells Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
53. Talisman Energy USA Inc., Pad ID: Yurkanin 03 014, ABR–201007033.R1, Columbia Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
54. Talisman Energy USA Inc., Pad ID: McMurray 01 031, ABR–201007054.R1, Canton Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
55. Talisman Energy USA Inc., Pad ID: 05 080 Young, ABR–201007080.R1, Warren Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
56. Talisman Energy USA Inc., Pad ID: Thorp 03 049, ABR–201007082.R1, Wells Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
57. Talisman Energy USA Inc., Pad ID: Watson 03 051, ABR–201007084.R1, Columbia Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
58. Talisman Energy USA Inc., Pad ID: 05 006 Ugliuzza L, ABR–201007086.R1, Pike Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
59. Talisman Energy USA Inc., Pad ID: Cummings 01 081, ABR–201007088.R1, Troy Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
60. Talisman Energy USA Inc., Pad ID: Kirkowski 01 066, ABR–201007091.R1, Canton Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
61. Talisman Energy USA Inc., Pad ID: Feusner 03 044, ABR–201007094.R1, Columbia Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
62. Talisman Energy USA Inc., Pad ID: Feusner 03 045, ABR–201007095.R1, Columbia Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
63. Talisman Energy USA Inc., Pad ID: Walters 05 001, ABR–201007096.R1, Herrick Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
64. Talisman Energy USA Inc., Pad ID: 05 004 Cooley P, ABR–201007099.R1, Orwell Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
65. Talisman Energy USA Inc., Pad ID: 05 002 Warner Valley Farm LLC, ABR–201007130.R1, Pike Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: August 18, 2015.
66. EOG Resources, Inc., Pad ID: PHC 23H/24H, ABR–20090917.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 24, 2015.
67. EOG Resources, Inc., Pad ID: PHC 28H/29H, ABR–20090918.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: August 24, 2015.
68. EOG Resources, Inc., Pad ID: PHC 20V, ABR–20100156.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 0.9990 mgd; Approval Date: August 24, 2015.
69. EOG Resources, Inc., Pad ID: PHC Pad S, ABR–201009023.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: August 24, 2015.
70. EOG Resources, Inc., Pad ID: PPHC Pad B, ABR–201103023.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: August 24, 2015.
71. EOG Resources, Inc., Pad ID: PHC Pad Z, ABR–201103024.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of

Up to 4.9990 mgd; Approval Date: August 24, 2015.

72. SWEPI LP, Pad ID: Broadbent 466, ABR–20100673.R1, Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 24, 2015.
73. SWEPI LP, Pad ID: Zeafla 747, ABR–20100682.R1, Jackson Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 24, 2015.
74. SWEPI LP, Pad ID: Camp Never Too Late 521, ABR–20100683.R1, Rutland Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 24, 2015.
75. SWEPI LP, Pad ID: Cruttenden 846, ABR–20100685.R1, Middlebury Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 24, 2015.
76. SWEPI LP, Pad ID: Anthony 564, ABR–201006111.R1, Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 24, 2015.
77. SWEPI LP, Pad ID: Costanzo 818, ABR–201006112.R1, Chatham Township, Tioga County, Pa.; Consumptive Use of Up to 1.0000 mgd; Approval Date: August 24, 2015.
78. SWEPI LP, Pad ID: Yaggie 704, ABR–201006113.R1, Union Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 24, 2015.
79. Anadarko E&P Onshore, LLC, Pad ID: Mac Pad A, ABR–201508001, Cascade Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 26, 2015.
80. Anadarko E&P Onshore, LLC, Pad ID: Brooks Family Pad A, ABR–201508002, Cascade Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 26, 2015.
81. Chesapeake Appalachia, LLC, Pad ID: Earnshaw, ABR–201508003, Mehoopany Township, Wyoming County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: August 26, 2015.
82. Cabot Oil & Gas Corporation, Pad ID: Teel P2, ABR–201508004, Dimock Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.2500 mgd; Approval Date: August 26, 2015.
83. SWEPI LP, Pad ID: Gee 848W, ABR–201508005, Middlebury Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: August 26, 2015.
84. EOG Resources, Inc., Pad ID: Ward M 1H, ABR–20090421.R1, Springfield Township, Bradford County, Pa.; Consumptive Use of Up to 1.9990 mgd; Approval Date: August 27, 2015.
85. EOG Resources, Inc., Pad ID: PHC 3H, ABR–20090424.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 0.4990 mgd; Approval Date: August 27, 2015.
86. EOG Resources, Inc., Pad ID: SGL 90A Pad, ABR–201008049.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: August 27, 2015.
87. EOG Resources, Inc., Pad ID: SGL 90D Pad, ABR–201103021.R1, Lawrence Township, Clearfield County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: August 27, 2015.
88. Tenaska Resources, LLC, Pad ID: Wilcox #1, ABR–20090803.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 0.9999 mgd; Approval Date: August 27, 2015.
89. Tenaska Resources, LLC, Pad ID: Strange, ABR–20100404.R1, Sullivan Township, Tioga County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: August 27, 2015.
90. Tenaska Resources, LLC, Pad ID: Golden Eagle, ABR–20100433.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: August 27, 2015.
91. Tenaska Resources, LLC, Pad ID: Chicken Hawk, ABR–20100434.R1, Sullivan Township, Tioga County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: August 27, 2015.
92. Tenaska Resources, LLC, Pad ID: Sparrow Hawk, ABR–201009044.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: August 27, 2015.
93. Tenaska Resources, LLC, Pad ID: Red Tailed Hawk, ABR–201011027.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: August 27, 2015.
94. EXCO Resources (PA), LLC, Pad ID: Dale Bower Drilling Pad #1, ABR–20100214.R1, Penn Township, Lycoming County, Pa.; Consumptive Use of Up to 8.0000 mgd; Approval Date: August 28, 2015.
95. EXCO Resources (PA), LLC, Pad ID: Emig Drilling Pad #1, ABR–20100452.R1, Cogan House Township, Lycoming County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: August 28, 2015.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: October 26, 2015.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2015–28272 Filed 11–5–15; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Office of Commercial Space Transportation; Notice of Intent To Prepare an Environmental Impact Statement (EIS), Open a Public Scoping Period, and To Hold a Public Scoping Meeting in Camden County, Georgia

AGENCY: The Federal Aviation Administration (FAA) is the lead Federal agency. The National Aeronautics and Space Administration and National Park Service are cooperating agencies for this EIS.

ACTION: Notice of Intent to prepare an EIS, open a public scoping period, and hold a public scoping meeting.

SUMMARY: This Notice provides information to Federal, State, and local agencies; Native American tribes; and other interested persons regarding the FAA's intent to prepare an EIS to evaluate the potential environmental impacts of issuing a Launch Site Operator License to the Camden County Board of Commissioners for a proposed commercial space launch site (''Spaceport Camden''). The Camden County Board of Commissioners proposes to construct and operate Spaceport Camden in an unincorporated area of Woodbine, in Camden County, Georgia. The FAA will prepare the EIS in accordance with the National Environmental Policy Act of 1969 (NEPA; 42 United States Code 4321 *et seq.*), the Council on Environmental Quality Regulations for Implementing the Procedural Provisions of NEPA (40 Code of Federal Regulations parts 1500–1508), and FAA Order 1050.1F, *Environmental Impacts: Policies and*

Procedures, as part of its licensing process. Concurrent with the NEPA process, the FAA is initiating National Historic Preservation Act Section 106 Consultation to determine the potential effects of the Proposed Action on historic properties. The FAA is also consulting with the U.S. Fish and Wildlife Service (USFWS) under Section 7 of the Endangered Species Act regarding potential impacts on federally-listed threatened and endangered species. Pursuant to the U.S. Department of Transportation Act of 1966, this EIS will comply with the requirements of Section 4(f) of the Act. Additional information is available online at: *http://www.faa.gov/about/office_org/headquarters_offices/ast/environmental/nepa_docs/review/documents_progress/camden_spaceport/.*

DATES: The FAA invites interested agencies, organizations, Native American tribes, and members of the public to submit comments or suggestions to assist in identifying significant environmental issues and in determining the appropriate scope of the EIS. The public scoping period starts with the publication of this Notice in the **Federal Register**. To ensure sufficient time to consider issues identified during the public scoping period, comments should be submitted to Ms. Stacey M. Zee, FAA Environmental Specialist, by one of the methods listed below no later than January 4, 2016. All comments will receive the same attention and consideration in the preparation of the EIS.

ADDRESSES: Comments, statements, or questions concerning scoping issues or the EIS process should be mailed to: Ms. Stacey M. Zee, FAA Environmental Specialist, Spaceport Camden County EIS c/o Leidos, 20201 Century Boulevard, Suite 105, Germantown, MD 20874. Comments can also be sent by email to *FAACamdenSpaceportEIS@Leidos.com*.

SUPPLEMENTARY INFORMATION:

Background

The FAA is preparing an EIS for the Camden County Board of Commissioners to construct and operate Spaceport Camden, a proposed commercial space launch site in an unincorporated area of Woodbine, in Camden County, Georgia. The County will be required to obtain a Launch Site Operator License from the FAA for the operation of the launch site. The EIS will consider the potential environmental impacts of the Proposed Action and the No Action Alternative; however, based on comments received during the scoping period, the FAA may analyze additional alternatives. The successful completion of the environmental review process does not guarantee that the FAA Office of Commercial Space Transportation would issue a Launch Site Operator License to the Camden County Board of Commissioners. The project must also meet all FAA requirements of a Launch Site Operator License. Individual launch operators proposing to launch from the site would be required to obtain a launch license.

Proposed Action

The Proposed Action is for the FAA to issue a Launch Site Operator License to the Camden County Board of Commissioners that would allow the Camden County Board of Commissioners to offer the commercial space launch site, Spaceport Camden, to commercial launch providers to conduct launch operations of liquid-fueled, medium-lift-class, orbital and suborbital vertical launch vehicles. Under the Proposed Action, the Camden County Board of Commissioners would construct and operate Spaceport Camden, which would include a vertical launch site, a landing zone, a control center complex, and a facility that includes visitor-viewing areas. Spaceport Camden would accommodate up to 12 vertical launches and up to 12 associated launch vehicle first-stage landings per year. In addition, there would be up to 12 static fire engine tests and up to 12 wet dress rehearsals per year.

The Camden County Board of Commissioners has signed an option to purchase approximately 4,000 acres of an approximately 12,000-acre industrial site on which to construct the spaceport, and is considering purchasing approximately another 7,800 acres of adjoining property in the same industrial complex. The proposed Spaceport Camden property is located in an unincorporated area of Woodbine, in Camden County, approximately 11.5 miles due east of the town of Woodbine, Georgia, in the extreme southeastern part of the state. Access to the site is at the eastern termination of Union Carbide Road, an extension of Harriett's Bluff Road (Exit 7 from I–95). The site is on the coast, surrounded by salt marshes to the east and south, and the Satilla River to the north. The property comprises uplands, salt marshes, and fresh water wetlands. Approximately 100 non-contiguous upland acres would be used for the launch pad, landing site, control center, and supporting facilities. Each of these facilities would be fenced to provide security and access control, as would the approximately 400 acres of uplands on which these facilities would be located. The remainder of the site, much of which is marshland, would be used as buffer.

The vertical launch facility would be approximately 23 acres in size and would include a launch pad and stand with its associated flame duct; propellant storage and handling areas; vehicle and payload integration facility; storage tanks; lightning protection systems; deluge water systems for local sound and vibration suppression; and other launch-related facilities and systems. The landing area would be approximately 11 acres in size and include a proposed 400 foot by 400 foot concrete pad located roughly in the center of the area, with fuel and oxidizer ''off load'' tanks, and related infrastructure. The control center complex would be located on the property at a safe distance from the launch and landing areas. The control center complex would house the site administration offices, a control room with related equipment, payload processing/check-out area, and a first-responder facility. This complex would be situated in an area of approximately 2.75 acres, and would consist of two buildings with a parking lot between them. There would be a similar facility constructed near the main entrance of the property that would mirror the control center complex in size, design and facilities, but would also include provisions for visitors and viewing launches.

Operations would consist of up to 12 launches and up to 12 associated launch vehicle first-stage landings per year. In addition, other operations could occur, including up to 12 static fire engine tests and up to 12 wet dress rehearsals per year. All vehicles would launch to the east over the Atlantic Ocean. Under the Proposed Action, the first stage of the launch vehicle could return to and land at Spaceport Camden, or would land in the Atlantic Ocean, either in the water or on a barge.

The potential environmental impacts of all proposed construction and operational activities, including those from launching orbital and suborbital vertical launch vehicles, will be analyzed in the EIS. The EIS will evaluate the potential environmental impacts associated with air quality; biological resources (including fish, wildlife, and plants); climate; coastal resources; Department of Transportation Act, Section 4(f); farmlands; hazardous materials, solid waste, and pollution prevention; historical, architectural, archeological and cultural resources;

land use; natural resources and energy supply; noise and noise-compatible land use; socioeconomics, environmental justice, and children's health and safety risks; visual effects; water resources (including wetlands, floodplains, surface waters, groundwater, and wild and scenic rivers). This analysis will include an evaluation of potential direct and indirect impacts, and will account for cumulative impacts from other relevant activities in the area of Camden County, Georgia.

Alternatives

The alternatives under consideration include the Proposed Action and the No Action Alternative; however, based on comments received during the scoping period, the FAA may analyze additional alternatives. Under the No Action Alternative, the FAA would not issue a Launch Site Operator License to the Camden County Board of Commissioners.

Scoping Meeting

A public scoping meeting will be held to solicit input from the public on potential issues that may need to be evaluated in the EIS. The scoping meeting will be held on Monday, December 7, 2015, from 5 p.m. to 8 p.m., at the Camden County Public Services Authority Recreation Center Community Room, 1050 Wildcat Drive, Kingsland, Georgia 31548. The meeting format will include an open-house workshop from 5:00 p.m. to 6:00 p.m. The FAA will provide an overview of the environmental process from 6:00 p.m. to 6:15 p.m., followed by a public comment period from 6:15 p.m. to 8:00 p.m. During the public comment period, members of the public may provide up to a 2-minute statement. The FAA will transcribe oral comments. Members of the public also may submit written or emailed comments. All comments received during the scoping period, whether provided in writing or verbally, will be given equal weight and will be taken into consideration in the preparation of the Draft EIS.

More information on the proposed project and the NEPA process is available on the project Web site at: *http://www.faa.gov/about/office_org/headquarters_offices/ast/environmental/nepa_docs/review/documents_progress/camden_spaceport/.*

Issued in Washington, DC, on: November 2, 2015.

Daniel Murray,

Manager, Space Transportation Development Division.

[FR Doc. 2015–28336 Filed 11–5–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. Docket No. FMCSA–2006–2575; FMCSA–2011–0193; FMCSA–2011–0194; FMCSA–2013–0183; FMCSA–2013–0186; FMCSA–2013–0188; FMCSA–2013–0189]

Qualification of Drivers; Exemption Applications; Diabetes

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions of 90 individuals from its rule prohibiting persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. FMCSA has statutory authority to exempt individuals from this rule if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: Each group of renewed exemptions are effective from the dates stated in the discussions below. Comments must be received on or before December 7, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. [Docket No. FMCSA–2006–2575; FMCSA–2011–0193; FMCSA–2011–0194; FMCSA–2013–0183; FMCSA–2013–0186; FMCSA–2013–0188; FMCSA–2013–0189], using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on January 17, 2008 (73 FR 3316).

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are from 8 a.m. to 5:30 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the Federal Motor Carrier Safety Regulations 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 90 individuals listed in this notice have recently become eligible for

a renewed exemption from the diabetes prohibition in 49 CFR 391.41(b)(3), which applies to drivers of CMVs in interstate commerce. The drivers remain in good standing with the Agency, have maintained their required medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period.

Exemption Decision

This notice addresses 90 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. These 90 drivers remain in good standing with the Agency, have maintained their required medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period. Therefore, FMCSA has decided to extend each exemption for a renewable two-year period. Each individual is identified according to the renewal date.

The exemptions are renewed subject to the following conditions: (1) That each individual submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) that each individual reports within 2 business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) that each individual submit an annual ophthalmologist's or optometrist's report; and (4) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. The following groups of drivers received renewed exemptions in the month of November and are discussed below.

As of November 1, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 17 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. (78 FR 50482; 78 FR 65754):

John K. Abels (IL)
Dean A. Bacon (IN)
Philip E. Banks (OH)
Anthony M. Bride (NJ)
Charles E. Dailey (AL)
Kenneth D. Denny (WA)
Adam M. Hogue (MS)
Allen D. LaFave (ND)
Greg P. Mason (NY)
Thomas D. Miller (MT)
Douglas A. Mulligan (KY)
David G. Peters (PA)
Robert J. Rispoli, Jr. (NY)
Mike P. Senn (MN)
Hames H. Suttles (AL)
Gregory F. Wendt (NE)
Michael J. Wickstrom (MI)

The drivers were included in Docket No. FMCSA–2013–0183. Their exemptions are effective as of November 1, 2015 and will expire on November 1, 2017.

As of November 6, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual, George J. Ehnot (PA), has satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (78 FR 56988; 78 FR 67459).

The driver was included in Docket No. FMCSA–2013–0186. The exemption is effective as of November 6, 2015 and will expire on November 6, 2017.

As of November 9, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 11 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. (78 FR 55460; 78 FR 69795):

Mark A. Blanton (IN)
Howard T. Cash (IL)
Heath J. Chesser (AL)
Kevin F. Connacher (PA)
Darryl A. Daniels (OH)
Carrie L. Frisby (CA)
Dean M. Keeven (MI)
Christopher A. Labudde (IL)
Brian A. Mankowski (IL)
Robert E. Welling (OH)
Keith Weymouth (ME)

The drivers were included in Docket No. FMCSA–2011–0193. Their exemptions are effective as of November 9, 2015 and will expire on November 9, 2017.

As of November 12, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 24 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. (78 FR 56988; 78 FR 67459):

Charles E. Andersen (MN)
Philip B. Blythe (IL)
Ryan T. Byndas (AZ)
Winfred G. Clemenson (WA)
Michael C. Crewse (IL)
James D. Crosson, Jr. (MN)
Bruce E. Feltenbarger (MI)
Charles A. Fleming (VA)
Brian W. Hannah (UT)
Michael P. Huck (MI)
Van K. Jarrett (KY)
Keith W. Lewis (MO)
Eugene M. Mikell (NH)
Ronny J. Moreau (NH)
James M. O'Rourke (MA)
Joshua T. Paumer (MT)
Vladimir B. Petkov (MO)
Luther S. Pickell (KS)
Robert J. Pulliam (AZ)
Andrew W. Sprester (ND)
Vincent J. Terrizzi, Sr. (PA)
Daniel C. Theis (FL)
Richard A. White (TN)
Mark A. Winning (IL)

The drivers were included in Docket No. FMCSA–2013–0186. Their exemptions are effective as of November 12, 2015 and will expire on November 12, 2017.

As of November 16, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 13 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. (76 FR 61140; 76 FR 71111):

Mark D. Andersen (IA)
David A. Basher (MA)
Brian H. Berthiaume (VT)
Eric D. Blocker, Sr. (NC)
Berry W. Campbell (WI)
Raymond A. Jack (WA)
Quency T. Johnson (WI)
Kenny B. Keels, Jr. (SC)
Jason M. Pritchett (MI)
Steven R. Sibert (MN)
Cassie J. Silbernagel (SD)
Lewis B. Taylor (IL)
James A. Terilli (NY)

The drivers were included in Docket No. FMCSA–2011–0194. Their exemptions are effective as of November 16, 2015 and will expire on November 16, 2017.

As of November 19, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual, Marshall H. Evans (IL), has satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (76 FR 63280; 76 FR 76398).

The driver was included in Docket No. FMCSA–2013–0188. The exemption

is effective as of November 19, 2015 and will expire on November 19, 2017.

As of November 20, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 22 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. (71 FR 58464; 71 FR 67201):

John N. Anderson (MN)
Allan C. Boyum (MN)
Terry L. Brantley (NC)
Steven E. Brechting (MI)
Scott A. Carlson (WI)
Joseph L. Coggins (SC)
Stephanie D. Fry (WY)
Robert W. Gaultney, Jr. (MD)
Paul T. Kubish (WI)
David M. Levy (NY)
Sterling C. Madsen (UT)
David F. Morin (CA)
Jeffrey J. Morinelli (NE)
Ronald D. Murphy (WV)
Charles B. Page (PA)
John A. Remaklus (OH)
Michael D. Schooler (IN)
Arthur L. Stapleton, Jr. (OH)
Carolyn J. Taylor (IN)
Jeffrey M. Thew (WA)
Barney J. Wade (MS)
Dennis D. Wade (IL)

The drivers were included in Docket No. FMCSA–2006–2575. Their exemptions are effective as of November 20, 2015 and will expire on November 20, 2017.

As of November 22, 2015, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual, Steven R. Auger (NH), has satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (76 FR 63295; 76 FR 76400).

The driver was included in Docket No. FMCSA–2013–0189. The exemption is effective as of November 22, 2015 and will expire on November 22, 2017.

Each of the 90 drivers in the aforementioned groups qualifies for a renewal of the exemption. They have maintained their required medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of the 90 drivers for a period of two years is likely to achieve a level of safety equal to that existing without the exemption. The drivers were included in docket numbers FMCSA–2006–2575; FMCSA–2011–0193; FMCSA–2011–0194; FMCSA–2013–0183; FMCSA–2013–0186; FMCSA–2013–0188; FMCSA–2013–0189.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by December 7, 2015.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 90 individuals from rule prohibiting persons with ITDM from operating CMVs in interstate commerce in 49 CFR 391.41(b)(3). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the medical condition of each applicant for an exemption from rule prohibiting persons with ITDM from operating CMVs in interstate commerce. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket numbers FMCSA–2006–2575; FMCSA–2011–0193; FMCSA–2011–0194; FMCSA–2013–0183; FMCSA–2013–0186; FMCSA–2013–0188; FMCSA–2013–0189 and click the search button. When the new screen appears, click on the blue ''Comment Now!'' button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2006–2575; FMCSA–2011–0193; FMCSA–2011–0194; FMCSA–2013–0183; FMCSA–2013–0186; FMCSA–2013–0188; FMCSA–2013–0189 and click ''Search.'' Next, click ''Open Docket Folder'' and you will find all documents and comments related to the proposed rulemaking.

Issued on: October 29, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–28316 Filed 11–5–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Limitation on Claims Against Proposed Public Transportation Projects

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: This notice announces final environmental actions taken by the Federal Transit Administration (FTA)

for projects in Albuquerque, NM, Chicago, IL, and Tempe, AZ. The purpose of this notice is to announce publicly the environmental decisions by FTA on the subject projects and to activate the limitation on any claims that may challenge these final environmental actions.

DATES: By this notice, FTA is advising the public of final agency actions subject to Section 139(l) of Title 23, United States Code (U.S.C.). A claim seeking judicial review of FTA actions announced herein for the listed public transportation projects will be barred unless the claim is filed on or before April 4, 2016.

FOR FURTHER INFORMATION CONTACT: Nancy-Ellen Zusman, Assistant Chief Counsel, Office of Chief Counsel, (312) 353–2577 or Terence Plaskon, Environmental Protection Specialist, Office of Environmental Programs, (202) 366–0442. FTA is located at 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 9 a.m. to 5:30 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FTA has taken final agency actions by issuing certain approvals for the public transportation projects listed below. The actions on the projects, as well as the laws under which such actions were taken, are described in the documentation issued in connection with the projects to comply with the National Environmental Policy Act (NEPA) and in other documents in the FTA administrative record for the projects. Interested parties may contact either the project sponsor or the relevant FTA Regional Office for more information on each project. Contact information for FTA's Regional Offices may be found at *http://www.fta.dot.gov.*

This notice applies to all FTA decisions on the listed projects as of the issuance date of this notice and all laws under which such actions were taken, including, but not limited to, NEPA [42 U.S.C. 4321–4375], Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303], Section 106 of the National Historic Preservation Act [16 U.S.C. 470f], and the Clean Air Act [42 U.S.C. 7401–7671q]. This notice does not, however, alter or extend the limitation period for challenges of project decisions subject to previous notices published in the **Federal Register**. The projects and actions that are the subject of this notice are:

1. *Project name and location:* Albuquerque Rapid Transit, Albuquerque, NM. *Project sponsor:* The City of Albuquerque. *Project description:* The proposed project would provide bus rapid transit service from the Unser Transit Center on the west side of Albuquerque to Tramway Boulevard on the east side, an overall length of approximately 14 miles, and construct exclusive lanes for rapid vehicles from Coors Boulevard to Louisiana Boulevard, a distance of approximately 8.75 miles. The project would also construct 20 stations, including 15 median stations and five curbside platforms. *Final agency actions:* No use determination of Section 4(f) resources; Section 106 finding of no adverse effect; project-level air quality conformity; and determination of documented categorical exclusion. *Supporting documentation:* Documented categorical exclusion pursuant to 23 CFR 771.118(d), dated August 26, 2015.

2. *Project name and location:* Lawrence to Bryn Mawr Modernization Project, Chicago, IL. *Project sponsor:* Chicago Transit Authority. *Project description:* The proposed project would replace the Lawrence, Argyle, Berwyn, and Bryn Mawr stations and approximately 1.3 miles of rail transit structural infrastructure on the Red and Purple lines in the Uptown and Edgewater community areas of Chicago. *Final agency actions:* Section 4(f) determination; a Section 106 Memorandum of Agreement, dated September 28, 2015; project-level air quality conformity; and Finding of No Significant Impact, dated October 1, 2015. *Supporting documentation:* Environmental Assessment, dated April 29, 2015.

3. *Project name and location:* Red-Purple Bypass Project, Chicago, IL. *Project sponsor:* Chicago Transit Authority. *Project description:* The proposed project would construct a fifth track bypass for the northbound Brown Line at Clark Junction, just north of Belmont station, and reconstruct approximately 0.3 miles of the mainline Red and Purple line tracks from Belmont station on the south to the stretch of track between Newport and Cornelia Avenues on the north. The bypass would provide a grade-separated junction allowing northbound Brown Line trains to cross unimpeded over and above north- and southbound Red Line tracks, as well as southbound Purple Line tracks, on a new aerial structure. *Final agency actions:* Section 4(f) determination; a Section 106 Memorandum of Agreement, dated September 28, 2015; project-level air quality conformity; and Finding of No Significant Impact, dated October 29, 2015. *Supporting documentation:* Environmental Assessment, dated May 19, 2015.

4. *Project name and location:* Tempe Streetcar, Tempe, AZ. *Project sponsor:* Valley Metro. *Project description:* The proposed project is an approximately three-mile long streetcar line that connects the emerging commercial district of Rio Salado Parkway along the Tempe Town Lake waterfront with Downtown Tempe and Arizona State University's main campus along Apache Boulevard to the Dorsey/Apache Boulevard light rail station. *Final agency actions:* No use determination of Section 4(f) resources; Section 106 finding of no adverse effect; project-level air quality conformity; and Finding of No Significant Impact, dated October 27, 2015. *Supporting documentation:* Environmental Assessment, dated July 2015.

Lucy Garliauskas,

Associate Administrator Planning and Environment.

[FR Doc. 2015–28319 Filed 11–5–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2015–0211; Notice No. 15–22]

Hazardous Materials: Notice of Suspension of Del-Med, Inc., Edison, NJ for DOT–SP 8308

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of suspension.

SUMMARY: This provides notice that transportation under the terms of DOT–SP 8308 has been suspended for Del-Med, Inc. formerly located in Edison, NJ.

DATES: The suspension discussed in this notice was effective October 21, 2015.

FOR FURTHER INFORMATION CONTACT: Mr. Ryan Paquet, Director, Approvals and Permits Division, Office of Hazardous Materials Safety, (202) 366–4535, PHMSA, 1200 New Jersey Avenue SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: DOT–SP 8308 authorizes the transportation in commerce of certain radioactive materials aboard highway vehicles when the combined transport index (TI) exceeds 50 or the separation criteria cannot be met. Paragraph 12.d. of DOT–SP 8308 requires quarterly reporting of: (i) The results of the radiation dosimetry program; (ii) a description of activities

conducted by the health physicist during the quarter; (iii) summaries of the results of the radiation level surveys and contamination surveys; (iv) any changes to the radiation safety program; (v) an estimate of the total TI transported during the quarter; and (vi) the total quarterly dose in person-rem for all monitored personnel.

Del-Med, Inc. of Edison, NJ missed filing their reports. The fourth quarter report for 2014 was due within 90 days of January 15, 2015; the first quarter report for 2015 was due within 90 days of April 15, 2015; and the second quarter report for 2015 was due within 90 days of July 15, 2015.

Pursuant to 49 CFR 107.121, PHMSA's Associate Administrator may modify, suspend or terminate a special permit or grant of party status, as appropriate, on finding that the holder or party knowingly has violated the terms of the special permit or an applicable requirement of this chapter in a manner demonstrating the holder or party is not fit to conduct the activity authorized by the special permit. Del-Med Inc.'s failure to file the reports required by the terms of DOT–SP 8308 constitutes a violation of the terms of the special permit. On September 11, 2015 PHMSA sent a letter proposing suspension of DOT–SP 8308, and offering Del-Med, Inc. an opportunity to respond within 30 days and show cause why the proposed action should not be taken. The US Postal Service was unable to deliver the letter. PHMSA's Office of Hazardous Materials Safety, Field Operations, attempted an inspection at the Edison, New Jersey facility and determined that Del-Med, Inc. is no longer active at that location. On October 21, 2015, PHMSA suspended Del-Med's status as a grantee to DOT–SP 8308 until such time that they can provide up-to-date quarterly reports and demonstrate that they are in compliance with the requirements of the special permit.

Issued in Washington, DC, on November 2, 2015.

Magdy El-Sibaie,

Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2015–28311 Filed 11–5–15; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35968]

San Pedro Railroad Operating Company, LLC, d/b/a San Pedro & Southwestern Railroad—Lease and Operation Exemption—Union Pacific Railroad Company

San Pedro Railroad Operating Company, LLC, d/b/a San Pedro & Southwestern Railroad (SPSR), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease and operate 7,422 feet of track owned by the Union Pacific Railroad Company (UPRR). This trackage, which is known as the Willcox Yard, is located at UPRR milepost 1074 in Willcox, Ariz. (the Line).

SPSR states that it has operated the Line pursuant to a lease entered into between SPSR and UPRR dated June 29, 2005 (the Initial Willcox Lease). According to SPSR, the Initial Willcox Lease expired on November 1, 2015. SPSR states that it has entered into a new lease with UPRR providing for SPSR's continued operation of the Line for a term of five years beginning on or about November 1, 2015 (the New Willcox Lease).[1]

The parties may consummate the transaction on or after November 22, 2015, the effective date of the exemption (30 days after the verified notice of exemption was filed).[2]

SPSR certifies that, as a result of this transaction, its projected revenues will not result in the creation of a Class II or Class I rail carrier and will not exceed $5 million.

SPSR states that the lease contains no interchange commitment between the parties.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than November 13, 2015 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35968, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy must be served on applicant's representative, John D. Heffner, Strasburger & Price, LLP, 1025 Connecticut Ave. NW., Suite 717, Washington, DC 20036.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: November 3, 2015.

By the Board.

Joseph H. Dettmar,

Acting Director, Office of Proceedings.

Tia Delano,

Clearance Clerk.

[FR Doc. 2015–28327 Filed 11–5–15; 8:45 am]

BILLING CODE 4915–01–P

[1] In addition to invoking the class exemption for the New Willcox Lease, SPSR is asking the Board to grant retroactive authority for the Initial Willcox Lease. However, the class exemption invoked by SPSR does not provide for retroactive effectiveness.

[2] Because SPSR amended its verified notice of exemption on October 23, 2015, that date is the official filing date and the basis for all subsequent dates.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35973]

SteelRiver Infrastructure Fund North America LP; SteelRiver Devco Holdings LLC; and SR Transportation Holdings LLC—Continuance in Control Exemption—West Belt Railway LLC

SteelRiver Infrastructure Fund North America LP (SteelRiver), SteelRiver Devco Holdings LLC (Devco), and SR Transportation Holdings LLC (SRTH) (collectively, Applicants), all noncarriers, have jointly filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of West Belt Railway LLC (WBRY), upon WBRY's becoming a Class III rail carrier.

This transaction is related to a concurrently filed verified notice of exemption in *West Belt RailwayÐLease & Operation Exemption Including Interchange CommitmentÐTerminal Railroad Association of St. Louis,* Docket No. FD 35972, in which WBRY seeks Board approval to lease from Terminal Railroad Association of St. Louis, and to operate, approximately 9.66 miles of rail line consisting of the following two segments: (1) The West Belt Industry Lead (WBIL), from milepost 1.07 at Adelaide Avenue to the end of the track at milepost 9.54; and (2) the Central Belt Industrial Lead, from the point of connection with the WBIL at milepost 9.54 to the end of the track, all located in the City of St. Louis, St. Louis County, Mo.

This transaction may be consummated on November 21, 2015, the effective date of the exemption (30 days after the verified notice of exemption was filed).

WBRY is owned by Devco. Devco is owned by SteelRiver. Devco and SRTH do not control any carriers. SteelRiver is owned by a diverse group of U.S. and foreign pension funds, insurance companies, and other investors. SteelRiver controls PRC Funding LLC, a noncarrier, which controls Patriot Funding LLC, a noncarrier, which controls PRC Holdings LLC, a noncarrier, which controls PRC Midco LLC, a noncarrier, which controls Patriot Rail Company LLC, (Patriot), a noncarrier. Patriot controls 13 Class III railroads. For a complete list of these rail carriers, and the states in which they operate, see the notice of exemption filed on October 22, 2015, in this proceeding. The notice is available on the Board's Web site at *WWW.STB.DOT.GOV*. The notice therefore seeks exemption for Devco and SRTH to continue in control of WBRY, and for SteelRiver to continue indirect control of WBRY when WBRY becomes a Class III rail carrier.

Applicants state that: (1) WBRY does not connect with any of the rail carriers controlled by Patriot; (2) the proposed transaction is not part of a series of anticipated transactions that would connect WBRY with each other or with any rail carriers controlled by Patriot; and (3) the proposed transaction does not involve a Class I rail carrier. The proposed transaction is therefore exempt from the prior approval requirements of 49 U.S.C. 11323 pursuant to 49 CFR 1180.2(d)(2).

Applicants state that the proposed transaction is intended to promote the investment objectives of Applicants and to improve the efficiency, financial strength, and ability of WBRY to meet the needs of shippers.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under §§ 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III carriers.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed by November 13, 2015 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35973 must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on: Thomas F. McFarland, Thomas F. McFarland, P.C., 208 South LaSalle Street, Suite 1890, Chicago, IL 60604.

Board decisions and notices are available on our Web site at: *WWW.STB.DOT.GOV*.

Decided: November 3, 2015.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Tia Delano,

Clearance Clerk.

[FR Doc. 2015–28335 Filed 11–5–15; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35972]

West Belt Railway LLC—Lease and Operation Exemption Including Interchange Commitment—Terminal Railroad Association of St. Louis

West Belt Railway LLC (WBRY), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to lease from Terminal Railroad Association of St. Louis, and to operate, approximately 9.66 miles of rail line consisting of the following two segments: (1) The West Belt Industry Lead (WBIL), from milepost 1.07 at Adelaide Avenue to the end of the track at milepost 9.54; and (2) the Central Belt Industrial Lead, from the point of connection with the WBIL at milepost 9.54 to the end of the track, all located in the City of St. Louis, St. Louis County, Mo., pursuant to a Lease Agreement (Agreement) dated October 14, 2015.[1]

This transaction is related to a concurrently filed verified notice of exemption in *SteelRiver Infrastructure Fund North America LP; SteelRiver Devco Holdings; & SR Transportation HoldingsÐContinuance in Control ExemptionÐWest Belt Railway LLC,* Docket No. FD 35973, in which SteelRiver Infrastructure Fund North America LP, SteelRiver Devco Holdings LLC, and SR Transportation Holdings LLC seek Board approval to continue in control of WBRY under 49 CFR 1180.2(d)(2), upon WBRY's becoming a Class III rail carrier.

WBRY certifies that the proposed lease and operation involves a provision in the Agreement that may limit future interchange with a third party connecting carrier (interchange commitment). As required under 49 CFR 1150.43(h)(1), WBRY has disclosed in its verified notice that the subject Agreement contains an interchange commitment that affects the interchange point in Rock Island Junction in the City of St. Louis. In addition, WBRY has provided additional information regarding the interchange commitment.

WBRY also certifies that the projected annual revenues do not exceed those that would qualify it as a Class III rail carrier and would not exceed $5 million.

The proposed transaction may be consummated on November 21, 2015, the effective date of the exemption (30 days after the verified notice of exemption was filed). If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed by November 13, 2015 (at least seven days prior to the date the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35972, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on applicant's representative, Thomas F. McFarland, Thomas F. McFarland, P.C., 208 South LaSalle Street, Suite 1890, Chicago, IL 60604.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: November 3, 2015.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Tia Delano,

Clearance Clerk.

[FR Doc. 2015–28334 Filed 11–5–15; 8:45 am]

BILLING CODE 4915–01–P

[1] WBRY filed a confidential, complete version of the Agreement with its notice of exemption to be kept confidential by the Board under 49 CFR 1104.14(a) without need for the filing of an accompanying motion for protective order under 49 CFR 1104.14(b). In a letter filed on October 23, 2015, WBRY submits the correct list of shippers in the response to 49 CFR 1150.33(h)(iii) that was incorrectly shown in its verified notice of exemption filed on October 22, 2015.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of Currency

FEDERAL RESERVE SYSTEM

[Docket No. OP–1465]

FEDERAL DEPOSIT INSURANCE CORPORATION

BUREAU OF CONSUMER FINANCIAL PROTECTION

SECURITIES AND EXCHANGE COMMISSION

Agency Information Collection; Submission for OMB Review; Joint Comment Request; Joint Standards for Assessing the Diversity Policies and Practices of Entities Regulated by the Agencies

AGENCY: Office of the Comptroller of the Currency (OCC); Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); Bureau of Consumer Financial Protection (CFPB); and Securities and Exchange Commission (SEC).

ACTION: Joint notice, request for comment, and notice of information collection to be submitted to the Office of Management and Budget (OMB) for review and approval under the Paperwork Reduction Act of 1995 (PRA).

SUMMARY: The OCC, FDIC, CFPB, and SEC (each, an Agency and collectively, the Agencies) have submitted to OMB a request for approval under the PRA of the collection of information discussed below. The Board (also an Agency and included in Agencies) reviewed the joint notice under the authority delegated to the Board by OMB. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before December 7, 2015.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the Agencies. All comments received will be shared among the Agencies.

OCC: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–NEW, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov.*

In general, OCC will enter all comments received into the docket and publish them on the *www.reginfo.gov* Web site without change, including any business or personal information that you provide such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may personally inspect and photocopy comments by visiting the OCC at 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may make an appointment by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to a security screening, prior to inspecting and photocopying comments.

Board: You may submit comments, identified by ''OMWI Policy Statement,'' by any of the following methods:

- *Agency Web site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.*
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Robert deV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room MP–500 of the Board's Martin Building (20th and C Streets NW.) between 9:00 a.m. and 5:00 p.m. on weekdays.

FDIC: You may submit comments on this information collection, which should refer to ''Joint Standards for Assessing Diversity Policies and Practices,'' by any of the following methods:

- *Agency Web site: http://www.fdic.gov/regulations/laws/federal/.* Follow the instructions for submitting comments on the FDIC Web site.
- *Email: comments@FDIC.gov.* Include ''Joint Standards for Assessing Diversity Policies and Practices'' in the subject line of the message.
- *Mail:* Gary A. Kuiper, Counsel, MB–3074, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

CFPB: You may submit comments, identified by the title of the information collection, ''Joint Standards for Assessing the Diversity Policies and Practices of Entities Regulated by the Agencies,'' or by the docket number (see below) using any of the following methods:

- *Electronic: http://www.regulations.gov* (*Docket Number: CFPB±2015±0042*). Follow the instructions for submitting comments.
- *Mail:* Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552.
- *Hand Delivery/Courier:* Consumer Financial Protection Bureau (Attention: PRA Office), 1275 First Street NE., Washington, DC 20002.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or social security numbers, should not be included.

SEC: Please direct your written comments to Pamela Dyson, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or send an email to *PRA_Mailbox@sec.gov* with ''SEC File 270–664 OMWI Policy Statement'' in the subject line of the message.

Additionally, commenters may send a copy of their comments to the OMB desk officer for the Agencies by mail to the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, New Executive Office Building Room 10235, 725 17th Street NW., Washington, DC 20503: By fax to (202) 395–6974; or by email to *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: For further information about the information collection discussed in this notice, please contact any Agency clearance officer named below. In addition, background documentation for

this information collection may be viewed at *www.reginfo.gov* or at the following locations:

OCC: Shaquita Merritt or Mary H. Gottlieb, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

Board: Nuha Elmaghrabi: Federal Reserve Clearance Officer, Office of the Chief Data Officer, Mail Stop K1–148, Board of Governors of the Federal Reserve System, Washington, DC 20551.

FDIC: Gary A. Kuiper, Counsel, MB–3074, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429, or send an email to *gkuiper@fdic.gov.*

CFPB: Darrin A. King, Paperwork Reduction Act Officer, 1700 G Street NW., Washington, DC 20552, (202) 435–9575, or email: *PRA@cfpb.gov.* Please do not submit comments to this email box.

SEC: Pamela Dyson, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to *PRA_Mailbox@sec.gov.*

SUPPLEMENTARY INFORMATION: Section 342 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act) required each Agency to establish an Office of Minority and Women Inclusion (OMWI) to be responsible for all matters of the Agency relating to diversity in management, employment, and business activities. The Dodd-Frank Act also instructed the OMWI Directors to develop standards for assessing the diversity policies and practices of entities regulated by their Agencies. The Agencies worked together to develop joint standards and, on June 10, 2015, they published a **Federal Register** notice (80 FR 33016) entitled ''Final Interagency Policy Statement Establishing Joint Standards for Assessing the Diversity Policies and Practices of Entities Regulated by the Agencies'' (Policy Statement).[1] The Policy Statement contains a collection of information within the meaning of the PRA (44 U.S.C. 3501 *et seq.*).

A. Overview of the Collection of Information

1. Description of the Collection of Information and Proposed Use

The title for this proposed collection of information is:

- Joint Standards for Assessing Diversity Policies and Practices.

The Policy Statement includes Joint Standards that cover ''Practices to Promote Transparency of Organizational Diversity and Inclusion.'' These standards contemplate that a regulated entity is transparent about its diversity and inclusion activities by making certain information available to the public annually on its Web site or in other appropriate communications, in a manner reflective of the entity's size and other characteristics. The information noted in these standards is the entity's diversity and inclusion strategic plan; its policy on its commitment to diversity and inclusion; progress toward achieving diversity and inclusion in its workforce and procurement activities (which may include the entity's current workforce and supplier demographic profiles); and employment and procurement opportunities available at the entity that promote diversity.

In addition, the Policy Statement includes standards that address ''Entities' Self-Assessment.'' These standards envision that the regulated entity conducts a voluntary self-assessment of its diversity policies and practices at least annually, provides information pertaining to this self-assessment to its primary federal financial regulator, and publishes information pertaining to its efforts with respect to the Joint Standards. The information provided to the Agencies will be used to monitor progress and trends among regulated entities with regard to diversity and inclusion in employment and contracting activities, as well as to identify and publicize leading diversity policies and practices.

2. Description of Likely Respondents and Estimate of Annual Burden

The collections of information contemplated by the Joint Standards will impose no new recordkeeping burdens as regulated entities will only publish or provide information pertaining to diversity policies and practices that they maintain during the normal course of business. The Agencies estimate that, on average, it will take a regulated entity approximately 12 burden hours annually to publish information pertaining to its diversity policies and practices on its Web site or in other appropriate communications and to retrieve and submit information pertaining to its self-assessment to its primary federal financial regulator.

The Agencies estimate the total burden for all regulated entities as follows:

Information Collection: Joint Standards for Assessing Diversity Policies and Practices.

Estimated Number of Respondents:
OCC: 215.
Board: 488.
FDIC: 398.
CFPB: 750.
SEC: 1,250.

Frequency of Collection: Annual.

Average Response Time per Respondent: 12 hours.

Estimated Total Annual Burden Hours:
OCC: 2,580 hours.
Board: 5,856 hours.
FDIC: 4,776 hours.
CFPB: 9,000 hours.
SEC: 15,000 hours.

Obligation to respond: Voluntary.

B. Solicitation of Public Comments

The Policy Statement included a 60-day notice requesting public comments on the collection of information. During the comment period, the Agencies collectively received four comment letters: Two from industry trade associations, one from an advocacy organization, and one from an individual.[2] The comments, which are described below, addressed the collection of information under the ''Entities Self-Assessment'' Joint Standards. (As noted above, these Joint Standards envision that a regulated entity provides self-assessment information to the OMWI Director of the entity's primary federal financial regulator.) The commenters also commented on aspects of the Policy Statement unrelated to the collection of information; these views are not relevant to this notice or the paperwork burden analysis and, accordingly, they are not addressed below.

After reviewing and considering the comments related to the collection of information, the Agencies have decided not to make any changes to the collection of information described in the 60-day notice.

1. Practical Utility of Information Collection

Two commenters addressed whether the collection of information pertaining to self-assessments will have practical utility. One commenter asserted that it is premature to gauge how useful information will be without knowing precisely what information the Agencies will request. The other commenter maintained that the information collection request in the Policy

[1] The National Credit Union Administration (NCUA) joined the Agencies in issuing the Policy Statement. However, the NCUA is issuing a separate **Federal Register** notice for PRA clearance.

[2] Separately, the NCUA received a comment letter from an industry trade association. The Agencies considered this comment and have included it in the discussion of comments below.

Statement will yield large variations in the information submitted and predicted that the information received will have little practical utility. This commenter argued that the Agencies should standardize the information they request so they are able to assess accurately the state of diversity and inclusion across the industry. The commenter's view is that standardization of the data request would enhance the quality, utility, and clarity of the collected information.

Although the Agencies have not specified the content or format for the information collection described in the Policy Statement, they anticipate that the information submitted to them will be similar in content, if not in form. They contemplate that regulated entities will organize their information collection around the categories in the Joint Standards. The Agencies also expect that the information they receive will help achieve the purpose of the collection, which is to allow the Agencies to identify trends in the financial services industry regarding diversity and inclusion in employment and contracting and to identify leading diversity policies and practices.

2. Specific Collection Instrument

Three commenters requested that the Agencies be more specific about the information collection. One commenter asked the Agencies to send questions that ''comport with how its member firms operate'' and that the information collection request allow entities to submit qualitative information to add context to quantitative submissions. Another commenter asked the Agencies to provide a ''robust'' example or template of the information the entities should submit. This commenter also recommended that the Agencies provide a non-exhaustive list of materials that respondents can use to compare against what they are planning to submit. The third commenter recommended that the Agencies develop a standardized collection instrument. This commenter noted that it had recommended standardized survey questions when it commented on the proposed Policy Statement. The commenter urged the Agencies to adopt a thorough framework for collecting specific and consistent data.

The Agencies appreciate the collection instrument recommendations and the offers to assist in developing an instrument. At this time, however, the Agencies have not developed a joint information collection instrument. The Agencies believe that the Policy Statement encourages regulated entities to provide information regarding their self-assessments in a manner reflective of the Joint Standards and that any such information received will be useful.

3. Assurance of Confidentiality

The Joint Standards addressing Self-Assessments provide that the entities submitting information may designate such information as confidential commercial information, where appropriate. Three commenters expressed concerns about whether the information submitted would remain confidential. One commenter indicated that its members are concerned that information submitted to their primary federal financial regulator might be provided, without context, to other regulators or to the U.S. Congress, leading to confusion or to the disclosure of competitive information. This commenter asked the Agencies to provide a clearer confidentiality policy and clarify that submissions will remain confidential unless the submitting entity expressly waives confidentiality. Similarly, another commenter stated that its members are concerned that third parties may have access to the information submitted and could use this information to the submitter's disadvantage. This commenter requested additional clarification regarding how the Agencies will use and protect submitted information, as well as a written statement providing assurance that the Agencies will not share the information with third parties.

The remaining commenter expressed concern that designating information as confidential will not guarantee protection from disclosure. The commenter observed that, if the public requests information under the Freedom of Information Act (FOIA), the regulated entity will be notified of the request and provided an opportunity to argue against disclosure. In the event that the regulated entity's argument does not prevail, the voluntarily submitted information could be released to the public.

Two of these commenters recommended that regulated entities be allowed to submit information anonymously. One commenter said its members might support the use of a third-party vendor that could capture and potentially anonymize submissions as a way to minimize information collection burden. The other commenter asserted that giving respondents the option to submit information anonymously would enhance the quality, utility, and clarity of the information, minimize burden, and address confidentiality concerns. This commenter also recommended that the Agencies allow submitters to classify themselves into general categories, such as by approximate asset size, number of employees, and geographic location.

The Agencies understand that regulated entities want assurances that the Agencies will treat the submitted information as confidential and will not disclose the information unless the submitter expressly waives confidentiality. To the extent that a submission includes confidential information, the Agencies will keep such information confidential to the extent allowed by law. The Agencies advise regulated entities submitting private information to follow their primary federal financial regulator's FOIA regulations with respect to designating information as confidential or seeking confidential treatment.

Finally, with respect to anonymity, the Agencies are concerned that anonymous submissions would be less useful than submissions in which the submitting entity is identified. As indicated in the Policy Statement, the OMWI Directors plan to reach out to regulated entities to discuss diversity and inclusion practices and methods of assessment, and these contacts will be more informative for both the Agencies and the entities if the Agencies know which submission came from which entity. However, the Agencies will reassess this matter over time.

4. Accuracy of Burden Estimate

The Agencies estimated that, annually, it would take an entity 12 burden hours, on average, to publish information pertaining to its diversity policies and practices on its Web site and to retrieve and submit self-assessment information to its primary federal financial regulator. One commenter stated that the Agencies grossly underestimated the time it would take to collect, categorize, and submit this information. The commenter asserted that retrieving diversity data is a time-consuming and labor-intensive task, particularly for entities with hundreds or thousands of employees located throughout U.S. and the world. In addition, the commenter maintained that an entity's submission would have to undergo a time-consuming review by legal counsel and others to assure accuracy and clarity before the entity could submit the information.

The Agencies note that the commenter did not provide an alternative estimate or formula for calculating this burden and that 12 hours is an estimated average. In the absence of more specific information, the Agencies do not have a basis for changing their burden estimate at this time. If, however, future feedback

indicates that the current estimate needs further refinement, the Agencies will consider adjusting their estimates accordingly.

5. Estimate of Start-Up Costs

One commenter asserted that it would take substantial IT, legal, and operational resources to put diversity data into a format appropriate for submission to a regulator. The commenter said that it could not provide an exact estimate of capital or start-up costs for submitting this information until an actual information request was available. In response, the Agencies note that there are no start-up costs associated with the collection of information contained in the Joint Standards. Furthermore, any costs incurred by a regulated entity, aside from the 12 burden hours discussed above to publish information pertaining to its diversity policies and practices on its Web site and to retrieve and submit self-assessment information to its primary federal financial regulator, will be incurred in the normal course of its business activities.

Written comments continue to be invited on:

(a) The necessity of the collection of information for the proper performance of the Agencies' functions, including whether the information will have practical utility;

(b) The accuracy of the Agencies' estimate of the information collection burden, including the validity of the methods and the assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information proposed to be collected;

(d) Ways to minimize the information collection burden on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The Agencies encourage interested parties to submit comments in response to these questions. Comments submitted in response to this notice will be shared among the Agencies. All comments will become a matter of public record.

Dated: October 8, 2015.

Stuart E. Feldstein,

Director, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, November 2, 2015.

Robert deV. Frierson,

Secretary of the Board.

Dated at Washington, DC, this 29th day of September, 2015.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

Dated: October 27, 2015.

Christopher D'Angelo,

Chief of Staff, Bureau of Consumer Financial Protection.

U.S. Securities and Exchange Commission.

Date: October 1, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–28369 Filed 11–5–15; 8:45 am]

BILLING CODE 4810–33–P; 6310–01–P; 6714–01–P; 4810–AM–P; 8011–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 2003–37; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments; correction.

SUMMARY: This document contains a correction to the Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (U.S.C. 3506(c)(2)(A)).

DATES: Written comments are still being accepted and should be received on or before December 28, 2015, to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Need for Correction

As published, Revenue Procedure 2003–37 contains an error that may prove to be misleading and is in need of clarification.

On page 66618, in the preamble, first column, under the caption **FOR FURTHER INFORMATION CONTACT:**, in the seventh line, the language ''internet at *Lanita.VanDyke@irs.ov*'' is corrected to read ''internet at *Lanita.VanDyke@irs.gov*''.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2015–28343 Filed 11–5–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee: National Academic Affiliations Council Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Federal Advisory Committee Act, 5 U.S.C. App. 2 that the National Academic Affiliations Council will be held December 8, 2015–December 9, 2015 in the Office of Academic Affiliations (OAA) Conference Room, 1800 G Street NW., Suite 870, Washington, DC. The December 8th sessions will begin at 9:00 a.m. and end at 4:30 p.m. On December 9th, 2015, sessions will begin at 9:00 a.m. and adjourn at 1:00 p.m.

The purpose of the Council is to advise the Secretary on matters affecting partnerships between VA and its academic affiliates.

On December 8, the Council will receive an update on the Veterans Equitable Resource Allocation formula for education support; discuss strategies for continued Graduate Medical Education (GME) expansion authorized by the 2014 Veterans Access, Choice, and Accountability (VACAA) Act; review the consolidation of non-VA provider programs directed by Public Law 114–41; and examine potential new joint ventures with academic affiliates. On December 9, the Council will explore the revised ethics rules for special government employees serving on Federal advisory committees; and discuss future possibilities for VA academic affiliations that strengthen the 70 year legacy of VA Policy memorandum No. 2. The Council will receive public comments from 12:30 p.m. to 12:45 p.m. on December 9, 2015.

Interested persons may attend and present oral statements to the Council. A sign-in sheet for those who want to give comments will be available at the meeting. Individuals who speak are invited to submit a 1–2 page summary of their comments at the time of the meeting for inclusion in the official meeting record. Oral presentations will be limited to five minutes or less, depending on the number of participants. Interested parties may also

provide written comments for review by the Council prior to the meeting or at any time, by email to, *Steve.Trynosky@va.gov,* or by mail to Stephen K. Trynosky J.D., MPH, MMAS, Designated Federal Officer, Office of Academic Affiliations (10A2D), 810 Vermont Avenue NW., Washington, DC 20420. Any member of the public wishing to attend or seeking additional information should contact Mr. Trynosky via email or by phone at (202) 461–6723.

Dated: November 3, 2015.

Jelessa Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2015–28310 Filed 11–5–15; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 80 Friday,
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Part II

Department of Labor

29 CFR Parts 29 and 30
Apprenticeship Programs; Equal Employment Opportunity; Proposed Rules

DEPARTMENT OF LABOR

29 CFR Parts 29 and 30

RIN 1205–AB59

Apprenticeship Programs; Equal Employment Opportunity

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The U.S. Department of Labor (DOL or Department) is issuing a Notice of Proposed Rulemaking (NPRM) to update the equal opportunity regulations that implement the National Apprenticeship Act of 1937. These regulations prohibit discrimination in registered apprenticeship on the basis of race, color, religion, national origin, and sex, and require that sponsors of registered apprenticeship programs take affirmative action to provide equal opportunity in such programs. The proposed rule would revise regulations to reflect changes made in October 2008 to Labor Standards for Registration of Apprenticeship Programs; update equal opportunity standards to include age (40 or older), genetic information, sexual orientation, and disability among the list of protected bases upon which a sponsor must not discriminate; strengthen the affirmative action provisions for sponsors by detailing mandatory actions a sponsor must take to satisfy its affirmative action obligations, and by requiring affirmative action for individuals with disabilities; and improve the overall readability of through restructuring and clarification of the text. In addition, the proposed rule would make technical, conforming amendments to current regulations.

DATES: Comments must be submitted by January 5, 2016.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 1205–AB59, by any one of the following methods:

- *Federal e-Rulemaking Portal www.regulations.gov*. Follow the Web site instructions for submitting comments.
- *Mail:* Please address all written comments (including disk and CD–ROM submissions) to Adele Gagliardi,, Administrator, Office of Policy Development and Research, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–5641, Washington, DC 20210.
- *Hand Delivery/Courier:* Adele Gagliardi, Administrator, Office of Policy Development and Research, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–5641, Washington, DC 20210.

Please submit your comments by only one method. The Department will post all comments received on *http://www.regulations.gov* without making any change to the comments, including any personal information provided. The *http://www.regulations.gov* Web site is the Federal e-rulemaking portal and all comments posted there are available and accessible to the public. The Department cautions commenters not to include their personal information such as Social Security Numbers, personal addresses, telephone numbers, and email addresses in their comments as such submitted information will become viewable by the public via the *http://www.regulations.gov* Web site. It is the responsibility of the commenter to safeguard his or her information. Comments submitted through *http://www.regulations.gov* will not include the commenter's email address unless the commenter chooses to include that information as part of his or her comment.

Postal delivery in Washington, DC, may be delayed due to security concerns. Therefore, the Department encourages the public to submit comments via the Web site indicated above.

Docket: For access to the docket to read background documents or comments received, go to the Federal eRulemaking portal at *http://www.regulations.gov*. The Department will also make all the comments it receives available for public inspection during normal business hours at the Office of Policy Development and Research (OPDR) at the above address. If you need assistance to review the comments, the Department will provide you with appropriate aids such as readers or print magnifiers. The Department will make copies of the rule available, upon request, in large print and as an electronic file on computer disk. The Department will consider providing the proposed rule in other formats upon request. To schedule an appointment to review the comments and/or obtain the rule in an alternate format, contact OPDR at (202) 693–3700 (VOICE) (this is not a toll-free number) or 1–800–877–8339 (TTY/ASCII).

FOR FURTHER INFORMATION CONTACT: Adele Gagliardi, Administrator, Office of Policy Development and Research, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–5641, Washington, DC 20210, *gagliardi.adele@dol.gov*, (202) 693–3700 (this is not a toll-free number). Individuals with hearing or speech impairments may access this telephone number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: This preamble is divided into three sections. Section I provides general background information on the development of the proposed revisions to 29 CFR parts 29 and 30 (part 29 and part 30, respectively). Section II is a section-by-section analysis of the proposed regulatory text. Section III covers the administrative requirements for this proposed rulemaking as mandated by statute and Executive Order.

I. Background

A. General Overview of Registered Apprenticeship

The National Apprenticeship Act of 1937 authorizes the Department to formulate and promote the furtherance of labor standards necessary to safeguard the welfare of apprentices. 29 U.S.C. 50. The responsibility for formulating and promoting these labor standards lies with the Department's Employment and Training Administration's (ETA) Office of Apprenticeship (OA). As part of its duties, OA registers apprenticeship programs that meet certain minimum labor standards. These standards, set forth at 29 CFR parts 29 and 30, are intended to provide for more uniform training of apprentices and to promote equal opportunity in apprenticeship.

Part 29 implements the National Apprenticeship Act by setting forth labor standards that safeguard the welfare of apprentices by prescribing policies and procedures concerning the registration, cancellation, and deregistration of apprenticeship programs; the recognition of State Apprenticeship Agencies (SAA) as Registration Agencies; and matters relating thereto. On October 29, 2008, the Department published an amended part 29 to provide a framework that supports an enhanced, modernized apprenticeship system. 73 FR 64402. These regulations can be accessed on OA's Web site at: *http://www.doleta.gov/oa/pdf/FinalRule29CFRPart29.pdf*.

Part 30 implements the National Apprenticeship Act by requiring registered apprenticeship program sponsors to provide equal opportunity for participation in their registered apprenticeship programs, and by protecting apprentices and applicants for apprenticeship from discrimination based on race, color, religion, national

origin, and sex. In addition, part 30 also requires that sponsors of registered apprenticeship programs take affirmative action to provide equal opportunity in such programs. The Department first published part 30 on December 18, 1963, at the direction of President Kennedy, who ordered that the Secretary of Labor, in implementing the National Apprenticeship Act and Executive Order 10925, require that the admission of young workers to apprenticeship programs be on a completely nondiscriminatory basis. 28 FR 13775. At that time, the regulations prohibited discrimination based on race, color, religion, and national origin. Coverage on the basis of sex was added in 1971, as was the requirement for sponsors with five or more apprentices to develop and implement a written affirmative action plan (AAP) for minorities. 36 FR 6810, April 8, 1971. In 1978, the Department amended these regulations to require inclusion of female apprentices in AAPs. 43 FR 20760, May 12, 1978. There have been no changes to these regulations since that time.

Registered apprenticeship is a combination of on-the-job training and related technical instruction in which workers learn the practical and theoretical aspects of a highly-skilled occupation. Apprenticeship programs are sponsored voluntarily by individual employers, employer associations, or Joint Apprenticeship Training Committees that partner organized labor with employers. In the U.S. today, there are more than 19,000 program sponsors representing over 200,000 employers who are offering registered apprenticeship training to more than 375,000 registered apprentices.[1]

OA oversees the National Registered Apprenticeship System. Federal staff members are directly responsible for registered apprenticeship activities in 25 States and provide technical assistance and oversight to 25 SAAs in the other 25 States. In these ''SAA States,'' the SAA has voluntarily requested recognition from the Secretary of Labor to serve as the entity authorized to register and oversee State and local apprenticeship programs for Federal purposes. Therefore, in those 25 States, the SAA, in accordance with Federal regulations, has responsibility for registering apprenticeship activities for Federal purposes.

Registered apprenticeship programs appear in traditional industries, such as construction (where the majority of registered programs has been) and manufacturing, as well as in new emerging ''high-growth'' industries, such as health care, information technology, and energy. High-growth industries are those sectors in the economy that are projected to add substantial numbers of new jobs to the economy or affect the growth of other industries, or they are existing or emerging businesses being transformed by technology and innovation requiring new skill sets for workers.[2]

B. Overview of the NPRM

In spring 2010, to inform the drafting of this NPRM, OA conducted a series of town hall meetings across the nation, a webinar, and listening sessions with the agency's stakeholders to elicit their recommendations for updating part 30. Through these efforts, OA received valuable input from a broad array of interested individuals, including SAAs; the National Association of State and Territorial Apprenticeship Directors (NASTAD); advocacy organizations; registered apprenticeship program sponsors such as labor-management organizations, employers, and employer associations; journeyworkers; former apprentices; and registered apprentices. This input addressed features of part 30 that work well, those that could be improved, and additional requirements that might help to effectuate the overall goal of ensuring equal opportunity for all individuals who are participating in or seeking to participate in the National Registered Apprenticeship System. Recurring themes in these town halls, webinars, and listening sessions included the need for increased outreach efforts to attract women and minorities; a focus on equal training and retention of apprentices; stricter enforcement of the Equal Employment Opportunity (EEO) obligations; clarification of complaint procedures; and progressive actions by Registration Agencies to achieve sponsor compliance with the regulations.

In developing the proposed rule, the Department also consulted with its Advisory Committee on Apprenticeship (ACA). Chartered under the Federal Advisory Committee Act, the ACA provides advice and recommendations to the Secretary of Labor (Secretary) on a wide range of matters related to apprenticeship. The ACA is comprised of approximately 30 members with equal representation of employers, labor organizations, and the public.

In January 2011, the ACA unanimously accepted a series of recommendations to revise part 30, prepared by its EEO regulations workgroup, and then formally provided those recommendations to the Department. In particular, the ACA recommended that the revised part 30: (1) Align with part 29; (2) link the part 30 regulatory requirements with apprenticeship programs' standard operating procedures, so that program sponsors can minimize administrative burden; (3) enhance program sponsors' accountability for compliance; (4) align requirements for outreach and recruitment activities with established national best practices; (5) allow maximum flexibility in selection procedures provided they are objective and specific; (6) provide for the use of local labor market information in establishing and updating utilization goals; and (7) require that all registered apprenticeship programs, regardless of size, adopt AAPs and selection procedures, supported by OA technical assistance.

This proposed rule is based on public input, ACA consultation, as well as OA's analysis of demographic patterns in apprenticeship discussed later in this preamble, and a literature review regarding barriers to entry, underutilization, and discrimination in apprenticeship and nontraditional occupations for women and minorities, and best practices to address these challenges. This NPRM proposes four general part 30 revisions: (1) Changes required to make part 30 consistent with the Labor Standards for Registration of Apprenticeship Programs set forth in part 29; (2) changes updating the scope of a sponsor's EEO obligations; (3) changes to enhance sponsors' affirmative action obligations and enforcement efforts by Registration Agencies; and (4) changes to improve the overall readability of part 30.

The first set of changes align the EEO regulations at part 30 with its companion regulations at part 29, and are necessary to ensure a cohesive, comprehensive regulatory framework for the National Registered Apprenticeship System. To that end, the Department proposes to revise or add several terms in 29 CFR 30.2, Definitions. These terms include ''administrator,'' ''apprentice,'' ''apprenticeship committee,'' ''apprenticeship program,'' ''pre-apprenticeship,'' ''employer,'' ''journeyworker,'' ''Office of Apprenticeship,'' ''Registration Agency,'' ''sponsor,'' and ''State Apprenticeship Agency.''

In addition, proposed part 30 incorporates the procedures set forth in part 29 for deregistration of

[1] Fiscal Year (FY) 2013 national results available at *http://doleta.gov/oa/data_statistics.cfm.*

[2] High growth industries include: Advanced manufacturing, construction, energy, health care, homeland security, hospitality, and transportation.

apprenticeship programs, derecognition of SAAs, and hearings. The use of a single set of procedures would streamline management of the National Registered Apprenticeship System. This would, for example, avoid the confusion of requiring two simultaneous proceedings when separate part 29 and part 30 issues arise in relation to a single registered apprenticeship program.

The second category of proposed changes addresses the fact that the EEO regulations for the National Registered Apprenticeship System have not been revised since 1978. The current EEO regulations prohibit discrimination in registered apprenticeship against individuals based on race, color, religion, national origin, and sex. Since 1978, however, the legal landscape for EEO has evolved. Within the context of the existing protected category of sex, for example, Congress passed the Pregnancy Discrimination Act in 1978, which amended Title VII to include, within the context of sex discrimination, discrimination on the basis of pregnancy, childbirth, and related medical conditions. The scope and analysis of pregnancy discrimination has been refined in Title VII case law throughout the years, up to and including the Supreme Court's recent holding in *Young* v. *United Parcel Serv., Inc.,* 135 S. Ct. 1338 (2015), addressing the obligations for providing workplace accommodations for pregnancy, childbirth, or related medical conditions. Further, the Equal Employment Opportunity Commission (EEOC), Department of Justice, the Department's Office of Federal Contract Compliance Programs (OFCCP), and several federal courts have held that discrimination on the basis of gender identity or transgender status falls within the ambit of sex discrimination.[3] Consistent with the Department's interpretation, this regulation interprets sex discrimination in line with these developments in the law.

The EEO landscape has evolved beyond those protected categories specifically enumerated in the regulations as well. In 1990, Congress enacted the Americans with Disabilities Act (ADA), 42 U.S.C. 12101 *et seq.,* prohibiting employers from discriminating in employment against qualified individuals on the basis of disability. In 2008, Congress passed the ADA Amendments Act (ADAAA), making it easier for an individual to establish that he or she has a disability within the meaning of the ADA. Most sponsors are subject to the ADA, as it applies to, among others, private employers with 15 or more employees, including part-time employees, and to joint labor management committees controlling apprenticeship and training. In 1996, the Equal Employment Opportunity Commission (EEOC) amended its regulations implementing the Age Discrimination in Employment Act (ADEA), subjecting apprenticeship programs to the ADEA's requirements, thus barring apprenticeship programs from setting upper age limit requirements or otherwise discriminating against apprentices age 40 or older on the basis of age. In 2008, Congress enacted the Genetic Information Nondiscrimination Act (GINA), which applies to joint-labor management training and apprenticeship programs, among others, and prohibits them from discriminating against employees or applicants because of genetic information. GINA prohibits the use of genetic information in making employment decisions and prohibits covered entities, including joint-labor management training and apprenticeship programs from requesting, requiring, or purchasing genetic information and strictly limits the disclosure of genetic information. Accordingly, this proposal would add age, disability, and genetic information to the list of bases upon which a sponsor must not discriminate, and revises part 30 throughout consistent with this change.

Additionally, the proposed rule adds sexual orientation to the list of protected bases. Since 1978, the legal landscape regarding employment discrimination related to sexual orientation has changed. Many employment practices that were not then widely recognized as discriminatory now constitute unlawful sex discrimination under title VII. In particular, it is now widely recognized that employment decisions made on the basis of stereotypes about how males and/or females are expected to look, speak, or act are a form of sex-based employment discrimination. *See Price Waterhouse* v. *Hopkins,* 490 U.S. 228, 250 (1989) (finding sex discrimination on basis of sex stereotyping). Following *Price Waterhouse,* the EEOC has concluded that discrimination against an individual because of that person's sexual orientation is a violation of Title VII. *David Baldwin* v. *Dep't of Transportation,* EEOC Appeal No. 0120133080 (July 15, 2015), at p. 14 (available at *http://www.eeoc.gov/decisions/0120133080.pdf*) (last accessed August 26, 2015). Also at the Federal level, in July 2014, President Obama issued Executive Order 13672, which amended Executive Order 11246 to add sexual orientation and gender identity to the list of bases for which discrimination by Federal contractors and subcontractors is prohibited. 79 FR 42971 (July 21, 2014). At the State and local level, the recognition of sexual orientation as a protected characteristic has expanded significantly. As of the publication of the proposed rule, 22 States and the District of Columbia, in addition to numerous additional counties and municipalities across the country, have passed statutes and ordinances explicitly prohibiting employment discrimination on the basis of sexual orientation in the public and private sectors.[4]

Adding sexual orientation as a protected characteristic is consistent with both the statutory authority requiring the formulation of ''labor standards necessary to safeguard the welfare of apprentices,'' 29 U.S.C. 50, and the Department's purpose and approach since part 30 was first established: To promote equality of opportunity in registered apprenticeship programs and prevent discrimination in the recruitment, selection, employment and training of apprentices by requiring, among other things, that apprentices and applicants for registered apprenticeship are selected according to objective and specific qualifications relating to job performance. 30 CFR 30.1 and 30.5. It is also consistent with the developing legal landscape in this area. While the proposal prohibits discrimination on the basis of sexual orientation, it does not require incorporating sexual orientation into written affirmative action plans, nor does it require sponsors to collect employee or applicant data on sexual orientation. This is consistent with the treatment of sexual orientation under OFCCP's affirmative action programs for federal contractors.

[3] *See Macy* v. *Holder,* Appeal No. 0120120821, 2012 WL 1435995, at *7 (EEOC) (2012), *available at http://www.eeoc.gov/decisions/0120120821%20Macy%20v%20DOJ%20ATF.txt* (last accessed August 26, 2015), on remand, Department of Justice (DOJ) Final Agency Decision, Agency Complaint No. ATF–2011–00751, DJ No. 187–9–149 (July 8, 2013); Memorandum from Attorney General Eric Holder to United States Attorneys and Heads of Department Components (Dec. 15, 2014), *available at http://www.justice.gov/file/188671/download* (last accessed August 26, 2015); OFCCP Directive 2014–02 (August 19, 2014), *available at http://www.dol.gov/ofccp/regs/compliance/directives/dir2014_02.html* (last accessed August 26, 2015); *see also, e.g., Glenn* v. *Brumby,* 663 F.3d 1312 (11th Cir. 2011); *Kastl* v. *Maricopa Cnty. Cmty. Coll. Dist.,* 325 F. App'x 492 (9th Cir. 2009); *Smith* v. *City of Salem,* 378 F.3d 566 (6th Cir. 2004); *Barnes* v. *City of Cincinnati,* 401 F.3d 729 (6th Cir. 2005); *Schroer* v. *Billington,* 424 F. Supp. 2d 203 (D.D.C. 2006).

[4] *https://www.aclu.org/maps/non-discrimination-laws-state-state-information-map* (last accessed Aug. 27, 2015).

The third category of proposed changes in this NPRM seeks to improve the effectiveness of program sponsors' required affirmative action efforts and of Registration Agencies' efforts to enforce and support compliance with this rule by, among other things, detailing specific mandatory actions a sponsor must take to satisfy its affirmative action obligations, including mandating certain actions that are merely suggested in the existing regulations. This NPRM also gives Registration Agencies more tools with which to promote compliance with affirmative action objectives. In addition, this NPRM expands affirmative action requirements in part 30 by requiring affirmative action for individuals with disabilities. These proposed enhancements are necessary because, despite the progress that has been made in some segments of the workforce since the promulgation of the existing part 30, the residual impact of longstanding discrimination continues to exclude historically disadvantaged worker groups from participation in registered apprenticeship. The Department has a strong interest in ensuring that its approval of a sponsor's apprenticeship program does not serve to support, endorse, or further private discrimination.

The fourth category of proposed changes in the NPRM would improve the overall readability of part 30 through a reorganization of the part 30 requirements, basic editing, and by providing clarifying language where needed. For instance, the Department proposes to make minor language changes for the purposes of clarity and adhering to plain language guidelines. This includes replacing the word ''shall'' with ''must'' or ''will'' as appropriate to the context. The Federal Plain Language Guidelines specify that use of the word ''shall'' is not only outdated, but also imprecise, as it ''could indicate either an obligation or a prediction.'' [5] In the past, the word ''shall'' has been used throughout the part 30 regulations to denote a requirement—something the word ''must'' does with greater clarity. In addition, the proposed rule would add a new section setting forth the effective date for this rule and for programs currently registered to come into compliance with the revised regulations.

Finally, the Department proposes to make a few minor, conforming changes in 29 CFR part 29, the companion rule to part 30. These changes do not alter any substantive requirements of part 29; rather, this NPRM makes minor revisions to part 29 in order to harmonize parts 29 and 30. The specific proposed revisions to parts 29 and 30 are explained in detail in Section II below.

C. Demographic Patterns of Women and Minorities in Apprenticeship

At the outset of the regulatory revision process, OA evaluated demographic changes in apprenticeship programs, apprenticeable occupations, and employment-related training programs in construction and non-construction industries. OA reviewed data in OA's Registered Apprenticeship Partners Information Data System (RAPIDS) [6] and analyzed workforce-related data from the Department of Commerce/Census Bureau's American Community Survey Data (ACS), the Current Population Survey (CPS), and the Bureau of Labor Statistics (BLS), all of which provide the Department with data on who is currently working in various labor market sectors. The representation of each demographic group employed in apprenticeable occupations provides a basis for estimating a minimum of who may be interested and/or available to enter into apprenticeships. OA recognizes that an estimate of availability for apprenticeship should more broadly include those with the potential capacity for registered apprenticeship, rather than being limited to those currently employed in the apprenticeable occupation. But even comparisons to the demographic characteristics of current employees in apprenticeable occupations and industries disclosed disparities in apprenticeship.

As described in more detail below, the Department has concluded from these data and other available analyses that women and minorities continue to face substantial barriers to entry into and, for some groups, completion of registered apprenticeships, despite their availability in industry sectors that include apprenticeable occupations. Barriers include:

- Lower than expected enrollment rates in registered apprenticeship for specific groups including, most notably, women and specific minority groups;
- To the extent that women and minorities participate in registered apprenticeships, women and almost all minority groups are concentrated in lower-paying occupations; and
- In the construction industry, barriers to apprenticeship program completion, which result in significant differences in completion rates amongst minority groups and for women in the construction industry.

Women in Apprenticeships

Women's enrollment in apprenticeship programs is significantly lower than expected. All women, regardless of race or ethnicity, are severely underrepresented in registered apprenticeship programs when compared to their share of the U.S. labor force. This disparity exists in comparison to the number of men in registered apprenticeships, and also in comparison to the number of women who are working in the wider civilian labor force. CPS data indicate that in 2014 the national labor force was 53.0 percent male and 47.0 percent female. Yet, as Table 1 illustrates, in the last decade, on average, women comprised only 7.1 percent of all new enrollments in registered apprenticeships, whereas men accounted for 92.9 percent—roughly the same as a decade ago.

TABLE 1 [7]—NEW ENROLLMENTS IN REGISTERED APPRENTICESHIP BY SEX, ALL INDUSTRIES

Year	% Female	% Male
2003	6.9	93.1
2004	7.7	92.3

[5] Federal Plain Language Guidelines at 25 (March 2011), available at *http://www.plainlanguage.gov/howto/guidelines/FederalPLGuidelines/FederalPLGuidelines.pdf* (last accessed Dec. 2, 2014).

[6] RAPIDS includes individual, apprentice-level data from the 25 states in which OA is the Registration Agency, and from the nine SAA states that have chosen to participate. However, unless otherwise stated, the tables and discussions of RAPIDS data are limited to the apprentice data managed by OA staff. We note that, currently, RAPIDS does not collect data regarding individuals with disabilities. The analysis excludes apprentice data maintained by State Apprenticeship Agencies, including those that participate in the RAPIDS database, since the majority of the SAA states provide limited aggregated information which does not lend itself to detailed statistical analysis of demographic characteristics. Given the unique structure of the Registered Apprenticeship system, OA believes that data managed by OA staff is an acceptable proxy for the nation as a whole, because this individual record dataset contains 62 percent of the total active apprentices nationwide (excluding active military members—USMAP) and a representative cross-section of 25 states.

TABLE 1 [7]—NEW ENROLLMENTS IN REGISTERED APPRENTICESHIP BY SEX, ALL INDUSTRIES—Continued

Year	% Female	% Male
2005	6.7	93.3
2006	7.1	92.9
2007	6.1	93.9
2008	6.7	93.3
2009	7.8	92.2
2010	8.3	91.7
2011	6.7	93.3
2012	7.5	92.5
2013	6.7	93.3
10 Year Average	7.1	92.9
CPS Labor Force Participation (2012)	47.0	53.0

When analyzed on an industry basis more pronounced disparities are disclosed. As seen in Table 2 below, of the seven high-growth industries identified by OA as particularly desirable for expansion opportunities for registered apprenticeship, all show huge disparities between male and female enrollment rates. For example, women are the vast majority of apprentices in the health care industry but are a fraction of apprentices in the construction and utilities industries.

TABLE 2 [8]—NEW ENROLLMENTS IN REGISTERED APPRENTICESHIP BY SEX AND INDUSTRY, 2013

Industry	% Female	% Male
Advanced Manufacturing	10.4	89.6
Construction	2.3	97.7
Utilities	1.8	98.2
Health Care and Social Assistance	95.5	4.5
Homeland Security Public Administration and National Security	16.1	83.9
Hospitality Educational Services	3.9	96.1
Transportation	3.7	96.3
CPS Labor Force Participation (2012)	47.0	53.0

The underrepresentation of women in registered apprenticeship programs for high-growth industries also is demonstrated by comparing the percentage of women working in high-growth industries with their percentage in registered apprenticeships in those same industries. As seen in Table 3 below, female enrollment was significantly below women's share of the workforce in the same six high-growth industries as in Table 2. Except for health care, these comparisons indicate that the representation of women enrolled in apprenticeship programs in these industries is significantly lower than the female rate of participation in these industries in the U.S. civilian labor force.

TABLE 3 [9]—COMPARISON OF NEWLY ENROLLED APPRENTICES BY SEX AND INDUSTRY TO CIVILIAN WORKFORCE CURRENTLY EMPLOYED IN THE INDUSTRY, 2013

Industry	Data	% Female	% Male
Advanced Manufacturing	Apprenticeship	10.4	89.6
	Workforce	29.0	71.0
Construction	Apprenticeship	2.3	97.7
	Workforce	8.9	91.1
Utilities	Apprenticeship	1.8	98.2
	Workforce	23.4	76.6
Health Care and Social Assistance	Apprenticeship	95.5	4.5
	Workforce	78.4	21.6
Homeland Security Public Administration and National Security.	Apprenticeship	16.1	83.9
	Workforce	45.4	54.6
Educational Services	Apprenticeship	3.9	96.1
	Workforce	68.6	31.4
Transportation	Apprenticeship	3.7	96.3
	Workforce	23.2	76.8

Apprenticeship = National Federal Workload only tracked in RAPIDS.
Workforce = Civilian Population Survey (CPS) February 2013.

[7] Source: Query of RAPIDS database—February 2014.

[8] Source: Query of RAPIDS database—February 2014.

[9] Source: Query of RAPIDS database—February 2014, and CPS, February 2013 (*http://www.bls.gov/cps/cpsaat16.htm*).

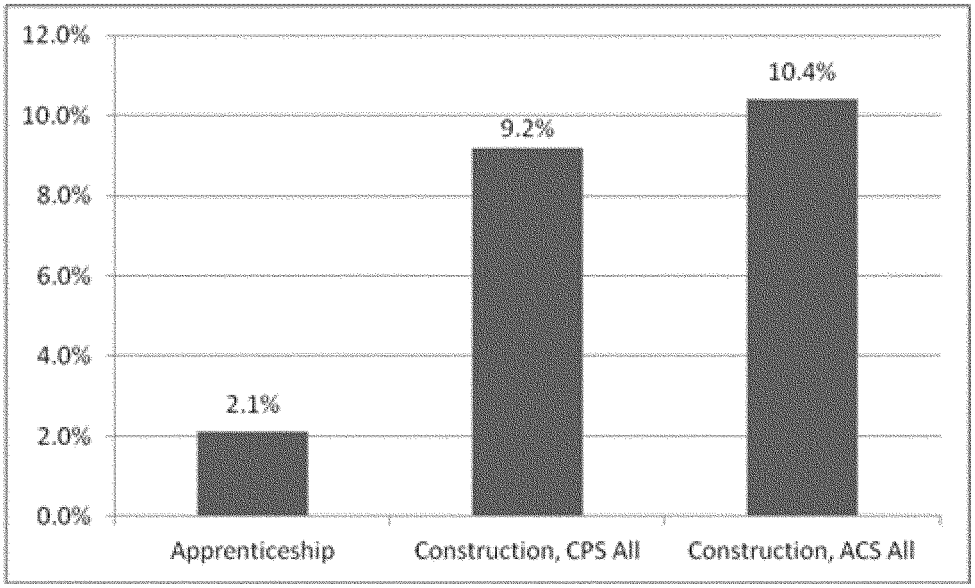
Women also are concentrated in apprenticeship programs for the lowest paying apprenticeable occupations. As shown in Table 4 below, women account for less than 10 percent of the enrollments in apprenticeship programs in the highest paid apprenticeable occupations, which include many construction occupations, but comprise typically over 80 percent of the enrollments in apprenticeship programs in the lowest paying apprenticeable occupations, such as nursing assistants in the health care industry.

TABLE 4 [10]—REPRESENTATION OF WOMEN IN APPRENTICESHIP PROGRAMS IN TOP 25 APPRENTICEABLE OCCUPATIONS

Category	Examples	Hourly Earnings	% Women
Best Paid Occupations	Electrician, Pipe Fitter, Painter	$25–$35 per hour	1–8.5
Intermediate Pay Level Occupations	Correction Officer, Cook/Chef	$15–$20 per hour	10–50
Lowest Paid Occupations	Child Care Development Specialist, Certified Nursing Assistant	Less than $15 per hour	85–99

Disparities between male and female enrollment rates are dramatic in the construction industry, where almost 60 percent of registered apprentices were enrolled in 2013, according to RAPIDS. As seen in Table 5 below, the representation of women in construction apprenticeship programs in 2013 (2.3 percent) was lower than the representation of women in construction industry occupations in all industries (8.9 percent according to the CPS and 9.9 percent according to the ACS).

Table 5[11]
Comparison of Various Female Utilization Rates
Construction Industry, 2013



This striking underrepresentation of women in construction apprenticeship programs is consistent with the historical underrepresentation of women in on-site construction occupations. Factors that affect women's representation in on-site construction occupations in the construction industry include negative stereotypes about women's ability to perform construction work and pervasive sexual harassment. These factors, together, act as a significant barrier to women entering the construction trades.[12] Women also may be the victims of discriminatory recruitment and selection procedures. The construction trades have traditionally used informal

[10] Source: Query of RAPIDS database for all active apprentices—February 2014.

[11] Table 5 uses multiple data sources. The RAPIDS database is the source for apprenticeship data. Other sources are the CPS and the ACS.

[12] *See, e.g.,* Permanent Commission on the Status of Women, ''Pre-Apprenticeship Construction Training Manual for Women.'' Hartford, CT, (2007); Byrd, B., ''Women in Carpentry Apprenticeship: A Case Study,'' 24 *Labor Studies Journal,* at 8 (Fall 1999); Ericksen, J., and Palladino Schultheiss D., ''Women Pursuing Careers in Trades and Construction,'' 36 *Journal of Career Development* at 69–70 (September 2009); Moir, S., Thomson, M., and Kelleher, C., ''Unfinished Business: Building Equality for Women in the Construction Trades,'' *Labor Resource Center Publications.* Paper 5 at 10–12 (2011); and ''Women in the Construction Workplace: Providing Equitable Safety and Health Protection,'' Health and Safety of Women in Construction (HASWIC) Workgroup, Advisory Committee on Construction Safety and Health (ACCSH), submitted to Occupational Safety and Health Administration (OSHA), Department of Labor (June 1999).

networks and referrals and word of mouth to recruit for open apprenticeships. Similarly, personal introductions and recommendations (as well as nepotism policies in the past) continue to be significant factors in selection for construction apprenticeships and work.[13] The problem of underrepresentation then perpetuates itself; because women have historically been underrepresented in construction apprenticeships and jobs, many of them may not have the connections necessary to receive information concerning these opportunities and be selected for them.[14] [15]

In addition to low enrollment rates, women complete apprenticeships in the construction industry at lower rates than men. As shown in Table 6 below, the 2011 completion rate indicates that women completed apprenticeships at a rate of 33.6 percent compared to 39.2 percent for men. Of the cohort of apprentices that completed in 2013, the most recent cohort for which the Department has completion rates, women's completion rate improved to a rate of 39.3 percent compared to 42.7 percent for men.

Table 6[16]
Apprentice Completion Rates in Construction Apprenticeship Programs, By Sex

2013 Completion Rate Cohort of Apprentices that Completed in FY 2012			
	Females	**Males**	**Total**
Number of Completions	379	16,510	16,889
Completion Rate	39.3%	42.7%	

2011 Completion Rate Cohort of Apprentices that Completed in FY 2011			
	Females	**Males**	**Total**
Number of Completions	340	16,662	17,002
Completion Rate	33.6%	39.2%	

Women can succeed in construction apprenticeship programs when provided equal opportunity. For example, a study of apprentices in Washington State during the 2005–2006 program year indicated that the participation rate of women apprentices in construction trades was 36 percent, much higher than the National Registered Apprenticeship System's average of 2.3 in construction apprenticeship programs.[17]

In conclusion, the data and literature about female participation in registered apprenticeship confirms:

- Significantly lower than expected enrollment rates for women in registered apprenticeship in general, as compared to the number of women in the workforce for industries that sponsor apprenticeships;
- Lower than expected completion rates for women relative to the rates for men; and
- Concentration of women in apprenticeship programs for the lowest paying occupations.

Minorities in Apprenticeship

Progress for racial minority groups and Hispanics or Latinos has been uneven and varies by group. Analyses reveal that tailored affirmative action efforts are necessary to ensure equal opportunity for racial minority groups and Hispanics or Latinos, who continue to face barriers to full participation in registered apprenticeship.

At the most macro level, a review of the nationwide enrollment data by industry reveals significant underutilization for some minority groups in some industries. For instance, in 2014, in manufacturing, Hispanics or Latinos comprised 15.8 percent of the civilian labor force, yet only represented 6.3 percent of the apprentice workforce.[18] Similarly, in the transportation industry, Hispanics or Latinos were 17.2 percent of the civilian labor force, but only 9.1 percent of the apprentice workforce. In utilities, Blacks or African Americans represented 8.9 percent of the civilian labor force, but only 5.9 percent of the apprentice workforce. In public administration and homeland security, Asians comprised 4.8 percent of the civilian labor force, but only 1.0 percent of the apprentice workforce.

More detailed analyses at the occupation level reveal further disparities. For instance, Hispanics or

[13] *See, e.g.,* Bilginsoy, C., ''The Hazards of Training: Attrition and Retention in Construction Industry Apprenticeship Programs,'' 57 *Industrial & Labor Relations Review,* at 54–67 (Oct. 2003); Byrd, B, ''Women in Carpentry Apprenticeship: A Case Study,'' 24 *Labor Studies Journal,* at 8–10 (Fall 1999).

[14] Bilginsoy, C., ''The Hazards of Training: Attrition and Retention in Construction Industry Apprenticeship Programs,'' 57 *Industrial & Labor Relations Review,* at 54–67, at 65 (Oct. 2003).

[15] The author of a study on women in carpentry apprenticeships suggests that apprenticeship programs in construction need to make a concerted effort to recruit females if they want to increase the number of female applicants. Byrd, B., ''Women in Carpentry Apprenticeship: A Case Study,'' 24 *Labor Studies Journal,* at 10 (Fall 1999).

[16] RAPIDS data. Completion rate means the percentage of an apprenticeship cohort who receives a certificate of apprenticeship completion within 1 year of the expected completion date. For more information see Bulletin FY 2011–07—Program Performance—Calculation of Registered Apprenticeship Program Completion Rates (*http://doleta.gov/OA/bu110/Bulletin_2011_07_Completion_Rates.pdf*).

[17] Washington State Workforce Training and Education Coordinating Board, ''Workforce Training Results: Apprenticeship,'' at 13 (Dec. 2008). A copy of the report is available at *http://www.wtb.wa.gov/Documents/WTR_Apprenticeship.pdf.*

[18] Source: Labor Force Statistics from the Current Population Survey, BLS (*http://www.bls.gov/cps/cpsaat18.htm*)

Latinos comprise 35.7 percent of active apprentices as painters yet represent 42.6 percent of painters in the civilian labor force.[19] Likewise, Hispanics or Latinos represent 11.1 percent of active apprentices as operating engineers, yet represent 16.5 percent of operating engineers in the civilian labor force. These disparities exist at the occupation level for Blacks or African Americans as well. For example, Blacks or African Americans represent 2.3 percent of active apprentices as building inspectors, yet represent 6.2 percent of building inspectors in the civilian labor force.[20] Likewise, Blacks or African Americans represent 2.4 percent of active apprentices as emergency medical technicians, yet represent 5.5 percent of these workers in the civilian labor force. The underrepresentation of Black or African American males in registered apprenticeship at the occupational level may be reflective of problems in the industry at large. Blacks or African Americans are underrepresented in many of the largest and highest paying apprenticeable occupations when compared to their utilization in similar occupations in other industries. In an analysis of 2005–2007 ACS data that drills down to the occupational level in the construction, extraction, and maintenance sector, researchers found that Black or African American men experience underrepresentation in 81 percent of the 67 precisely defined occupations that comprise this sector.[21]

In addition, minority groups tend to be concentrated in lower paying occupations. RAPIDS data for major occupations (those with the greatest numbers of total apprentices) for which earnings data are readily available show that both Hispanics or Latinos and Blacks or African Americans, for example, account for a smaller percentage of apprentices enrolled in apprenticeship programs in the highest paid apprenticeable occupations, and have a relatively greater representation in the lower paying apprenticeable occupations. Specifically, Blacks or African Americans make up less than 8 percent of the apprentice workforce for the highest paying apprenticeable occupations, such as electricians and plumbers, which earn on average $23.80/hour, but comprise 14.0 percent and 21.7 percent of lower paying occupations, such as construction laborers and correctional officers, which earn on average $12.31/hour and $18.77/hour, respectively. Likewise, Hispanics or Latinos make up less than 23 percent of higher paying apprenticeable occupations, such as elevator installers and repairers, which earn on average $36.85/hour, but comprise 35.7 percent and 45.1 percent of lower paying apprenticeable occupations, such as roofers and painters, which earn on average $16.95/hour.[22]

Furthermore, RAPIDS data reveal that there are challenges for minority groups in completion rates as well. For example, the 2013 completion rate for Blacks or African Americans in the construction industry, was 30.3 percent. This rate was significantly lower compared to Whites, who completed their apprenticeship programs at a rate of 46.7 percent. In conclusion, the data about minority participation in apprenticeship indicates the following:

- Progress has been made over the last 30 years for minority participation in registered apprenticeship, but it has been uneven across minority groups;
- Disparities continue to exist for some groups depending on industry, occupation, and geographic area;
- Minority groups are concentrated in apprenticeship programs in the lower paying occupations; and
- Completing apprenticeship programs has been a challenge for some minority groups.

These findings indicate that affirmative action, while necessary to ensure that minorities have an equal opportunity to apprentice, must be tailored to address the specific disparities by minority group, and by occupation, industry, and geographic area.

People With Disabilities in Apprenticeship

The Department believes strongly that including people with disabilities in apprenticeship affirmative action efforts is crucial to affording them equal opportunity in registered apprenticeship. Individuals with disabilities experience high levels of unemployment. According to the Survey of Income and Program Participation (SIPP) by the U.S. Census Bureau that collected data from May through August 2010, individuals with disabilities comprise approximately 16.6 percent (one sixth) of the working age population.[23] Yet, the unemployment rate of working age individuals with disabilities and the percentage of working age individuals with disabilities who are not in the labor force remain significantly higher than for those without disabilities.[24] According to 2012 data from BLS, 17.8 percent of working age people with disabilities were in the labor force in March 2011, compared with 63.9 percent of working age people with no disability.[25] The unemployment rate for working age people with disabilities was 13.4 percent, compared with a 7.9 percent unemployment rate for working age individuals without a disability. Ensuring individuals with disabilities have fair access to the employment training opportunities offered by registered apprenticeship programs through inclusion in affirmative action efforts can be important in opening doors to good jobs for people with disabilities.

The detailed Section-by-Section Analysis below identifies and discusses all proposed changes in each section. The Department welcomes comments on all of the provisions discussed below.

II. Section-by-Section Analysis

Title of the Rule

The current title of the rule is Equal Employment Opportunity in Apprenticeship and Training. The Department proposes to delete the phrase ''and Training'' to clarify that the rule applies specifically to apprenticeship programs registered under the National Apprenticeship Act, and not to other training programs for which the Department has responsibility. This updated title is consistent with recent revisions to the name of the Department's agency with responsibility for registration of apprenticeship programs, and implementation of the National Apprenticeship Act. Currently, this agency is ETA's OA. In 1963, when the part 30 regulation was first promulgated, and then in 1978, when it was last amended, the Department's apprenticeship agency was entitled the

[19] Source: Query of RAPIDS database—February 2014 and Labor Force Statistics from the Current Population Survey, BLS (*http://www.bls.gov/cps/cpsaat11.htm*).

[20] Source: Query of RAPIDS database—February 2014 and Labor Force Statistics from the Current Population Survey, BLS (*http://www.bls.gov/cps/cpsaat11.htm*).

[21] Hamilton, D, Algernon A., and William D., Jr., ''Whiter Jobs, Higher Wages: Occupational Segregation and the Lower Wages of Black Men.'' Economic Policy Institute, Washington, DC (Feb. 2011).

[22] Mean hourly earnings from the 2012 National Occupational Employment and Wage Estimates, BLS (*http://www.bls.gov/oes/current/oes_nat.htm*).

[23] Matthew W. Brault, ''Americans With Disabilities: 2010,'' U.S. Census Bureau (2012), *http://www.census.gov/prod/2012pubs/p70-131.pdf.*

[24] The working age population consists of people between the ages of 16 and 64, excluding those in the military and people who are in institutions.

[25] Source: Persons with a disability: Labor force characteristics (June 2013), BLS (*http://www.bls.gov/news.release/disabl.nr0.htm*).

Bureau of Apprenticeship and Training. In recent years, the agency's name was formally changed to the Office of Apprenticeship (OA).

Purpose, Applicability, and Relationship to Other Laws (§ 30.1)

In general, § 30.1 of the current part 30 condenses scope and purpose in one paragraph and outlines the general topics covered by part 30 in the same paragraph. The Department proposes several minor revisions to enhance the readability of this section.

First, the title of proposed § 30.1 would be revised to read ''Purpose, applicability, and relationship to other laws'' to better inform the public about what this section addresses. Second, proposed § 30.1 is divided into three paragraphs: § 30.1(a) would set forth the purpose of the rule; § 30.1(b) would address to whom the rule applies; and § 30.1(c) would discuss how this regulation relates to other laws that may apply to the entities covered by this regulation. In addition, proposed § 30.1 would delete the text indicating that part 30 addresses the registration of apprenticeship programs, because the registration of apprenticeship programs is covered only by part 29. Proposed § 30.1 also would add in § 30.1(a) that the required contents of a sponsor's affirmative action program are covered under part 30.

Proposed § 30.1(a) would add age (40 or older), genetic information, sexual orientation, and disability to the list of bases set forth in the rule upon which sponsors of registered apprenticeship programs must not discriminate. As discussed above, since 1978, when this rule was last amended, EEO law has evolved with the application of the ADEA and GINA to apprenticeship programs, the passage of the ADA, the issuance of Executive Order 13672, and the legal developments with respect to discrimination related to sexual orientation. By adding age (40 or older), genetic information, sexual orientation, and disability to the list of protected bases, the Department is better able to fulfill its charge to protect the welfare of apprentices and ensure admission to apprenticeship is on a ''completely non-discriminatory basis,'' as directed by President Kennedy. Moreover, the addition of these bases to the list of those upon which a sponsor must not discriminate ensures that the National Registered Apprenticeship System's regulatory framework affords the same protections to these individuals as it does for others, and it will bring the National Registered Apprenticeship System into alignment with the protected bases identified in the various Federal, State, and local laws already applicable to many apprenticeship sponsors.

For greater clarity and to establish parity with parallel provisions in the ADA, proposed § 30.1(c) also would include a paragraph explaining that part 30 does not invalidate or limit the remedies, rights, and procedures under any Federal law, or the law of any State or political subdivision, that provides greater or equal protection for individuals based on race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability. Proposed § 30.1(c) additionally recognizes as a defense to a charge of violation of this part that a challenged action is required or necessitated by another Federal law or regulation, or that another Federal law or regulation prohibits an action that would otherwise be required by this part.

The Department recognizes that program sponsors and Registration Agencies may need technical assistance with implementing these proposed regulations with respect to individuals with disabilities. Therefore, ETA will partner closely with the Department's Office of Disability Employment Policy (ODEP) to provide significant technical assistance tools and sub-regulatory policy and program guidance to assist program sponsors with improving their EEO practices with respect to individuals with disabilities and Registration Agencies with enforcing the EEO requirements set forth in this proposed rule. There are many resources immediately available to assist apprenticeship program sponsors in meeting their proposed EEO obligations for individuals with disabilities. For instance, the Job Accommodation Network, a free service provided by ODEP, provides one-on-one guidance to employers with expert and confidential guidance on workplace accommodations and disability employment issues.

Definitions (§ 30.2)

Proposed § 30.2 would revise and re-designate existing definitions and would add certain terms used in part 29 that apply also to part 30. The terms added from part 29 are: ''administrator,'' ''apprentice,'' ''apprenticeship committee,'' ''apprenticeship program,'' ''electronic media,'' ''employer,'' ''journeyworker,'' ''Office of Apprenticeship,'' ''Registration Agency,'' ''sponsor,'' and ''State Apprenticeship Agency.'' The proposed definitions for these terms are identical to those set forth in part 29.

In addition, because the Department proposes to include disability among the list of protected bases covered by part 30, proposed § 30.2 would add several new terms relevant to defining disability and disability discrimination standards. These are: ''direct threat,'' ''disability,'' ''major life activities,'' ''physical or mental impairment,'' ''qualified applicant or apprentice,'' ''reasonable accommodation,'' and ''undue hardship.'' The proposed definitions for these terms are taken directly from title I of the ADA, as amended by the ADAAA (effective January 1, 2009), and from the EEOC regulations implementing the ADA at 29 CFR part 1630, to the extent the ADAAA did not provide the definition. The Department intends that these proposed terms will have the same meaning as what was set forth in the ADAAA and implemented by the EEOC in 29 CFR part 1630. 76 FR 16978.

Likewise, because the Department proposes to add genetic information to the list of protected bases, proposed § 30.2 would include a definition of the term ''genetic information''. This proposed definition is taken directly from GINA and from the EEOC's implementing regulations at 29 CFR part 1635. The Department intends that this term will have the same meaning as what is set forth in GINA and implemented by the EEOC in 29 CFR part 1635.

Proposed § 30.2 also would add definitions for several new terms: ''pre-apprenticeship program,'' ''ethnicity,'' ''race,'' and ''selection procedure.'' The current part 30 regulations refer to ''programs of pre-apprenticeship'' in the requirements for AAPs in § 30.4. However, there is no standard definition or even application of the term ''pre-apprenticeship.'' Over the past several decades, pre-apprenticeship programs have been structured in numerous ways, depending on the partnerships, funding availability, and geographic area. The Aspen Institute recently completed a survey of pre-apprenticeship programs in the construction industry [26] and found a wide range of models, including those focused on placing participants into registered apprenticeship programs, while others are basically job preparation/readiness or career exploration programs oriented toward placing participants into a wide range of positive outcomes (job placement, placement into higher education) not formally linked to a registered apprenticeship program. On November 30, 2012, the Department circulated a

[26] Available on-line at *http://www.aspenwsi.org/WSIwork-sector.asp.*

Training and Employment Notice (TEN 13–12), Defining a Quality Pre-Apprenticeship Program and Related Tools and Resources, to inform the public workforce system about the pre-apprenticeship program definition and quality framework, as well as to promote tools and materials to improve the consistency and quality of pre-apprenticeship programs. The pre-apprenticeship definition and quality framework incorporated the following elements: Approved training and curriculum; strategies for long-term success; access to appropriate support services; promoting greater use of registered apprenticeship to increase future opportunities; meaningful hands-on training that does not displace paid employees; and facilitated entry and/or articulation.

The definition for ''pre-apprenticeship'' in the proposed rule would provide greater clarity and uniformity by establishing required components and suggested elements for pre-apprenticeship programs consistent with the TEN 13–12. The required components would be: Provision of structured workplace education and training; collaboration among apprenticeship program sponsors, community-based organizations, and educational institutions; and formal instruction that introduces participants to competencies, skills, and materials used in one or more apprenticeable occupations. This proposed definition also would include an optional provision for the offering of supportive services such as transportation, child care, and income support to assist participants to successfully complete the program.

Regarding the terms ''ethnicity'' and ''race,'' for purposes of recordkeeping and affirmative action, the terms ''ethnicity'' and ''race'' would have the same meaning as under the Office of Management and Budget's standards for the classification of Federal data on race and ethnicity found at *http://www.whitehouse.gov/omb/fedreg_1997standards/*, or any successor standards. ''Ethnicity'' would refer to the following designations: Hispanic or Latino; and Not Hispanic or Latino. The term ''race'' would refer to the following designations: White; Black or African American; Native Hawaiian or Other Pacific Islander; Asian; and American Indian or Alaska Native.

Regarding the term ''selection procedure,'' for consistency, the Department proposes to use the parallel definition found in the Uniform Guidelines on Employee Selection Procedures (UGESP) at 41 CFR part 60–3, because program sponsors are already required to comply with those regulations under the current part 30 and should be familiar with that definition.

Proposed § 30.2 would remove several terms that are no longer encompassed within the part 30 regulation itself. These are: ''Secretary,'' ''state apprenticeship council,'' ''state apprenticeship program,'' and ''state program sponsor.''

Equal Opportunity Standards Applicable to All Sponsors (§ 30.3)

Section 30.3 of the current part 30 is divided into five paragraphs and sets forth the required equal opportunity standards for registered apprenticeship programs. As currently structured, § 30.3 requires that a sponsor: Not discriminate on the basis of race, color, religion, national origin, and sex (§ 30.3(a)(1) and (2)); engage in affirmative action (§ 30.3(a)(3)); incorporate an equal opportunity pledge into its apprenticeship program standards (§ 30.3(b)); and, for programs with five or more apprentices, adopt an affirmative action program, as required by § 30.4, and a selection procedure, as required by § 30.5 (§ 30.3(c)).

Current § 30.3 also provides an exemption from the affirmative action program and selection procedure requirements for those programs already subject to an approved EEO program (§ 30.3(e)) and for those programs with fewer than five apprentices (§ 30.3(f)). In addition, § 30.3 discusses the impact of part 30 on programs ''presently registered'' as of the effective date of the regulations, and sets forth the registration requirements relating to sponsors seeking a new program registration (§ 30.3(c)). The Department finds the current regulatory structure confusing and in need of reorganization. The proposed rule seeks to reorganize § 30.3 for clarity purposes.

Proposed § 30.3 would remove paragraphs (c) through (f) and would incorporate them elsewhere in the rule, because these paragraphs do not pertain to the equal opportunity standards set forth in § 30.3. Instead, they pertain to: The effective date of the part 30 regulations for programs presently registered (current § 30.3(c)); the registration requirements for sponsors seeking registration of new programs (current § 30.3(d)); and the bases for exemption from the requirement to develop an affirmative action program (current § 30.3(e) and (f)). The reason behind removing these paragraphs and placing them elsewhere in the rule will be discussed in detail later in the preamble.

Proposed § 30.3 is divided into three paragraphs, each paragraph addressing an equal opportunity standard required of sponsors. Proposed § 30.3(a) would set forth the general prohibition against discrimination on the basis of race, color, religion, national origin, and sex—the bases listed in the current part 30—and would add a prohibition against discrimination on the basis of age (40 or older), genetic information, sexual orientation, and disability. The addition of these bases to the types of discrimination already prohibited by part 30 would align the Department's EEO regulations for registered apprenticeship with the Federal, State, and local anti-discrimination laws already applicable to many apprenticeship program sponsors, as discussed previously. These laws apply to many employers, including labor organizations and joint labor-management committees operating registered apprenticeship programs or other training or retraining programs, including an on-the-job training program, provided that the employer (and in this case the sponsor) employs the requisite threshold of individuals for coverage. Further, many employer's internal EEO policies already prohibit discrimination on these grounds, legal requirements notwithstanding.

Proposed § 30.3(a) also would incorporate the concepts set forth in the current regulation (§ 30.3(a)(1) and (2)) in a framework similar to that used in other equal opportunity laws. Section 30.3(a)(1) and (2) of the current part 30 address the sponsor's duty to not discriminate; therefore, these paragraphs would be consolidated. The Department proposes this change to clarify that the discrimination standards and defenses applied under part 30 are the same as those applied under the other major EEO laws that apply to sponsors in determining whether a sponsor has engaged in an unlawful employment practice, including title VII of the Civil Rights Act of 1964 (title VII), the ADEA, GINA, and the ADA. In enforcing the nondiscrimination obligations of sponsors set forth in this part, OA follows Title VII legal principles and case law, and will do the same with regard to ADEA, GINA, and the ADA.

Proposed § 30.3(b) requires that all sponsors, regardless of size, take affirmative steps to provide equal opportunity in apprenticeship. Under § 30.3(a)(3) of the current part 30, all sponsors are required to engage in affirmative action to provide equal opportunity, and those with five or more apprentices also are required to adopt an AAP. The current part 30 also

articulates affirmative action obligations for those developing AAPs; however, the regulation is silent as to what is required of sponsors in order to fulfill these general obligations.

Proposed § 30.3(b) fills this gap by identifying the minimum affirmative steps that all sponsors, regardless of size, must take in order to ensure equal opportunity in apprenticeship programs. By clearly specifying the requirements, this revised regulatory structure is intended to ensure that *all* sponsors take the necessary steps to ensure that they fulfill their EEO obligations under part 30, and become more aware of the effect their employment practices have on EEO. This revised framework furthers the Department's strategic vision of promoting and protecting opportunity for all workers and employers by ensuring that apprenticeship program sponsors develop and fully implement a program that seeks to break down the barriers to fair workplaces.

Proposed § 30.3(b)(1) requires sponsors to designate an individual to be responsible and accountable for overseeing the sponsor's commitment to equal opportunity in apprenticeship, including the development of the sponsor's affirmative action program, as required by § 30.4. This designation is expected to facilitate a sponsor's compliance with part 30 by creating a self-monitoring mechanism within each registered apprenticeship program, therefore institutionalizing each sponsor's commitment to equal opportunity. The Department anticipates that this requirement would be fulfilled by individuals who are currently providing coordination and administrative oversight functions for the program sponsor. For example, in the Department's experience, many program sponsors identify a specific individual to serve as an apprenticeship coordinator, who oversees and manages the apprenticeship program, including the EEO components.

Proposed § 30.3(b)(2) requires the sponsor to develop internal procedures to communicate its equal opportunity and affirmative action obligations to apprentices, applicants for apprenticeship, and personnel involved in the recruitment, screening, selection, promotion, training, and disciplinary actions of apprentices. This requirement would be similar to that set forth in § 30.4(c)(4) of the current part 30, which addresses internal communication of the sponsor's equal opportunity policy. However, proposed § 30.3(b)(2) would be required of *all* sponsors, regardless of size, and would make this communication mandatory; under the current part 30, internal communication of the sponsor's equal opportunity policy is merely a suggested activity for meeting the sponsor's outreach and recruitment obligations.

Furthermore, proposed § 30.3(b)(2) also identifies the specific minimum activities that a sponsor is required to undertake to satisfy the obligation to disseminate internally the sponsor's equal opportunity policy. Compliance with this requirement should not be particularly onerous or burdensome, given that the increasingly standard use of technology—particularly regarding the use of electronic media for communications and records maintenance—would readily enable a program sponsor to comply with these requirements. Proposed § 30.3(b)(2) requires a sponsor to: (i) Publish its equal opportunity pledge in apprenticeship standards and in appropriate publications; (ii) post the pledge on bulletin boards, including through electronic media, accessible to apprentices and applicants for apprenticeship; (iii) conduct orientation and periodic information sessions for apprentices and all of a program sponsor's personnel involved in the recruitment, screening, selection, promotion, training, and disciplinary actions of apprentices to inform, remind, and ensure that these individuals understand how to implement the sponsor's equal opportunity policy with regard to apprenticeship; and (iv) maintain records necessary to demonstrate compliance with this requirement.

Proposed § 30.3(b)(2)(i) carries forward the existing requirement in current § 30.3(b) for program sponsors to include the equal opportunity pledge in their apprenticeship standards, and slightly expands the provision by requiring sponsors to also post the pledge in other appropriate publications such as apprentice and employee handbooks, policy manuals, newsletters, and Web sites. Proposed § 30.3(b)(3)(iii) also requires program sponsors to include the equal opportunity pledge in the notification of apprenticeship openings to be provided to recruitment sources.

Proposed § 30.3(c) updates the specific language of the equal opportunity pledge, as discussed below. Therefore, sponsors will need to make a one-time revision of the apprenticeship standards to incorporate the revised equal opportunity pledge. With regard to posting the pledge in other appropriate publications and including the pledge in the notification of apprenticeship openings to recruitment sources, the Department expects that program sponsors would insert the revised equal opportunity pledge, if it is not already included in such publications, or would update the existing pledge that may already be included as they routinely update these materials. Cost and burden associated with the updating and/or inserting the equal opportunity pledge would be incorporated in program sponsors' existing efforts to maintain these publications and notifications, and therefore will not require frequent updates or changes. Many apprenticeship program sponsors' Web sites, apprenticeship handbooks, and existing publications already include the equal opportunity pledge. Therefore, the Department anticipates very little additional burden would result from compliance with proposed § 30.3(b)(2)(i) and (ii).

The orientation and information sessions required by proposed § 30.3(b)(2)(iii) underscore the sponsor's commitment to equal opportunity and its affirmation action obligations. These sessions would also institutionalize a sponsor's EEO policies and practices, providing a mechanism by which the sponsor may inform everyone connected with the apprenticeship program of the sponsor's obligations under part 30, and ensure that all individuals involved in the program understand these obligations and the policies instituted to implement them.

Given that sponsors operate apprenticeship programs in numerous industries and occupations, involving a wide range of working conditions and environments, the Department recognizes that it is unrealistic to prescribe in the proposed rule the exact nature and frequency of these sessions. This specificity would be contrary to the industry-driven nature of registered apprenticeship. Accordingly, the recordkeeping requirement in proposed § 30.3(b)(2)(iv) would allow the program sponsor and the Registration Agency a more industry-driven, effective review, to ensure that a sponsor is in compliance with its general obligation to engage in affirmative steps to ensure equal opportunity in registered apprenticeship.

Proposed § 30.3(b)(3) requires a sponsor, regardless of size, to ensure that its outreach and recruitment efforts for apprentices extend to all persons available and qualified for apprenticeship within the sponsor's recruitment area regardless of race, sex, ethnicity, or disability status. This universal recruitment and outreach requirement would foster awareness of opportunities for apprenticeship among all individuals regardless of their race,

sex, ethnicity, and disability status. This requirement, which is consistent with the corresponding requirement in current part 30, is intended to meet the Department's vision of promoting and protecting opportunity for all workers and employers. Sponsors would be required to develop a list of recruitment sources that would generate referrals from all demographic groups, including women, minorities, and individuals with disabilities, with contact information for each source and would be required to notify these sources in advance of any apprenticeship opportunities. The proposal does not specify how far in advance this notification must be, understanding that unique circumstances may affect the amount of advance notice that can be given, but states that at least 30 days advance notice is preferred. Examples of relevant recruitment sources include, but are not limited to, the public workforce system's One-Stop career centers and local workforce investment boards, community-based organizations, community colleges, vocational and technical education schools, pre-apprenticeship programs, and Federally-funded, youth job-training programs such as YouthBuild and Job Corps or their successors. A sponsor's notification to these recruitment sources could be conducted through a number of mechanisms, including but not limited to in-person meetings, distribution of form letters sent via email and/or postal mail, social media networks, and other options that may develop as the use of technology for information distribution continues to evolve. These specific requirements are meant to institutionalize a sponsor's commitment to affirmative action and to ensure that the sponsor is fulfilling its general obligation to engage in affirmative action.

Proposed § 30.3(b)(4) would introduce a section entitled, ''Maintain workplace free from harassment, intimidation, and retaliation,'' which requires a sponsor to develop and implement procedures to ensure that its apprentices are not harassed because of their race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability, and to ensure that its workplace is free from harassment, intimidation, and retaliation. In support of this requirement and to ensure an environment in which all apprentices feel safe, welcomed, and treated fairly, sponsors would be required to: (i) Communicate to all personnel that harassing conduct will not be tolerated; (ii) provide anti-harassment training to all personnel; (iii) make all facilities and apprenticeship activities available without regard to race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, and disability, except that if the sponsor provides restrooms or changing facilities, the sponsor must provide separate or single-user rest rooms and changing facilities to assure privacy between the sexes; and (iv) establish and implement procedures for filing, processing, and timely resolving complaints about harassment based on race, color, religion, national origin, sex, sexual orientation, age (40 or older), and disability. Because harassment is a form of employment discrimination that violates Federal laws applicable to most sponsors, including title VII, the ADEA, GINA, ADA, and Executive Order 11246 (as amended by Executive Order 13672), the steps outlined above will not impose any new burdens on sponsors who already must take the necessary action to prevent and eliminate harassment in the workplace.

The intent of proposed § 30.3(b)(4) would be to reduce workplace harassment and retaliation. The Department expects that sponsors' compliance with the obligations of proposed § 30.3(b)(4) ultimately will lead to an improvement in the retention rates of apprentices that are currently under-represented in apprenticeship programs so that they not only begin but also complete apprenticeships, and continue on as skilled journeyworkers in their respective occupations.

Proposed § 30.3(b)(5) requires all sponsors to comply with all applicable Federal and State laws and regulations requiring EEO without regard to race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability. A sponsor who fails to comply ultimately would be subject to enforcement actions, including possible deregistration. In essence, proposed paragraph (b)(5) merely carries forward the current § 30.10.

The Department does not expect that the steps outlined in proposed § 30.3(b) will increase a sponsor's compliance burden. Rather, these proposed steps are representative of the kinds of good faith efforts the Department has required to date for a sponsor to meet its EEO and affirmative action obligations under the current part 30.

Finally, proposed § 30.3(c) would carry forward the requirement set forth in the current § 30.3(b) for an equal opportunity pledge, but would make three important changes to this pledge. First, consistent with the expanded scope of the proposed regulation, proposed § 30.3(c) revises the pledge by adding age (40 or older), genetic information, sexual orientation, and disability to the list of bases upon which a sponsor must not discriminate. Second, it adds a parenthetical after sex discrimination specifying that pregnancy and gender identity discrimination are included within sex discrimination. Third, the proposed paragraph clarifies that a sponsor may include additional protected bases in the pledge, but must not exclude any of the bases protected under part 30.

Affirmative Action Programs (§ 30.4)

Current § 30.4 of part 30 sets forth the regulatory requirements with respect to affirmative action programs, addressing: The adoption of an affirmative action program in § 30.4(a); the definition of affirmative action in § 30.4(b); the requirements for broad outreach and recruitment in § 30.4(c); the mandate that a sponsor include goals and timetables where underutilization occurs in § 30.4(d); the factors for determining whether goals and timetables are needed in § 30.4(e); the establishment and attainment of goals and timetables in § 30.4(f); and that the Secretary of Labor will make available to program sponsors data and information on minority and female labor force characteristics in § 30.4(g). Exemptions from the requirement to adopt an affirmative action program are found in the current part 30 at § 30.3(e) and (f).

The proposed rule substantially restructures § 30.4 to streamline, clarify, update, and strengthen the affirmative action requirements.

Proposed § 30.4(a) would set forth the definition of and purpose for an affirmative action program, so that sponsors understand at the outset what the Department means by the term ''affirmative action program.'' This proposed definition is consistent with how the Department has defined the term in its regulations implementing the affirmative action requirements of Executive Order 11246 at 41 CFR part 60–2 applicable to supply and service Federal contractors and subcontractors. Current § 30.4(b) defines an affirmative action program as ''not mere passive non-discrimination'' and states that ''[i]t is action which will equalize opportunity in apprenticeship so as to allow full utilization of the work potential of minorities and women.'' Proposed § 30.4(a) elaborates on that definition and states that the premise underlying an affirmative action program is that absent discrimination, a sponsor's apprenticeship program generally will reflect the sex, race,

ethnicity, and disability profile of the labor pools from which the sponsor recruits and selects. Proposed paragraph (a) explains that, in addition to identifying and correcting underutilization, affirmative action programs also are intended to institutionalize the sponsor's commitment to equality by establishing procedures to monitor and examine the sponsor's employment practices and decisions with respect to apprenticeship, so that the practices and decisions are free from discrimination and barriers to equal opportunity are identified and addressed.

Proposed § 30.4(a) also makes clear that the commitments contained in an affirmative action program are not intended and must not be used to discriminate against any applicant or apprentice on the basis of race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability. This proposed definition is more expansive than the one in § 30.4(b) of the current part 30, and is intended to explain in more detail what constitutes an affirmative action program.

While the development and maintenance of an affirmative action program under these regulations is an integral tool in the pursuit of equal employment opportunity for all, it need not be an unduly burdensome undertaking. Thousands of employers, including large employers, have established apprenticeship programs with affirmative action plans under the existing regulations, and many have maintained and grown the number of apprenticeships, the diversity of their workforce, and the skill of their individual workers as a result. While these proposed regulations add some new obligations to the affirmative action program, they greatly streamline and clarify the AAP as a whole, making it simpler to understand what compliance means and easier to measure and achieve meaningful success—both for existing apprenticeship programs and for the many companies looking to create apprenticeship programs now and into the future.

Having established the definition and purpose of an affirmative action program, proposed § 30.4(b) sets forth who must adopt an affirmative action program. This proposed paragraph would require that unless otherwise exempted by proposed § 30.4(d), each sponsor must develop and maintain an affirmative action program, and set forth its program in a written plan. This language differs from current § 30.4(a), which does not indicate that some sponsors may be exempted from this requirement. The timeframe for preparing and submitting the written plan is set forth in proposed § 30.20. The details of the timing are discussed in greater detail in the discussion of that section, but in general, sponsors will have at least one year for the preparation and approval of the first plan under these proposed regulations, allowing ample time for sponsors to understand and implement their obligations. Further, during this period, the Registration Agency will provide technical assistance to sponsors seeking advice or clarification on the creation, drafting, and submission of its written plan.

The submission of the written plan to the Registration Agency is not an annual obligation; rather, the regulations specify that sponsors need only submit their current written plan to OA upon request. Thus, while sponsors will generally need to maintain and update their written AAPs annually for internal purposes (or potentially every two years, if the conditions in § 30.4(e), discussed below, are met), reviews will be less frequent. Further, the written AAP need not be a lengthy document. Sample written AAPs under the current regulations are available for review on OA's Web site as a model for sponsors to use in creating their own written plans, and many of the elements in this model can be readily adopted by new sponsors.[27] While these proposed regulations add a disability component to the AAP, this will not significantly expand the length of the written AAP.

The Department proposes to replace the current § 30.4(c) requirements related to outreach and positive recruitment with proposed § 30.8, discussed later in the preamble, which addresses the regulatory requirements related to targeted outreach, recruitment, and retention.

Proposed § 30.4(c) instead would provide an outline of the required elements of an affirmative action program in order to provide a roadmap to sponsors at the outset of what is required. Proposed § 30.4(c) would mandate that an affirmative action program include five elements: (1) Utilization analyses for race, sex, and ethnicity; (2) establishment of utilization goals for race, sex, and ethnicity, if necessary; (3) establishment of utilization analyses and goal setting for individuals with disabilities; (4) targeted outreach, recruitment, and retention, if necessary; and (5) a review of personnel processes.

Proposed § 30.4(c) also would identify the sections within the larger proposed rule that would address each of these elements. This type of roadmap is lacking in the current part 30. We believe this outline of required elements will help to facilitate a sponsor's compliance with the requirements of proposed § 30.4 by serving as a checklist in determining whether the sponsor has met all of the affirmative action program requirements.

Proposed § 30.4(d) sets forth, in one location, the two existing exemptions to the requirement that a sponsor develop an affirmative action program. These exemptions can be found in the current rule at § 30.3(e) (programs subject to an approved equal employment opportunity program) and § 30.3(f) (programs with fewer than five apprentices). Both exemptions are carried forward into the proposed rule at § 30.4(d) with one minor revision. Paragraph (e) currently exempts sponsors from the AAP requirement if they have an approved equal employment opportunity program providing for affirmative action under either title VII of the Civil Rights Act or Executive Order 11246. In light of the proposal to add disability to the list of protected bases for nondiscrimination and to the affirmative action requirements, such an exemption without change would fail to recognize that qualified individuals with disabilities are now protected from discrimination under part 30 and will benefit from affirmative action under the proposed rule. Therefore, the Department proposes to revise this exemption by requiring that a sponsor have an approved equal employment opportunity program under title VII of the Civil Rights Act and agree to extend such program to include individuals with disabilities, or have approved affirmative action programs under both Executive Order 11246 and section 503 of the Rehabilitation Act, which are administered by OFCCP and apply to Federal contractors and subcontractors with qualifying contracts. This would ensure that all protected bases set forth in the proposal would be addressed and that the sponsor is taking the appropriate actions to ensure that protected individuals are employed as apprentices and advanced in employment. This particular exemption can now be found in the proposed rule at paragraph (d)(2) of proposed § 30.4, which addresses the requirement to conduct affirmative action programs. This re-designation from § 30.3, which discusses equal opportunity standards, to § 30.4, which addresses affirmative

[27] *See http://www.doleta.gov/oa/bul10/Bulletin%202010-11a_AppendixC_inj.pdf (last accessed Sept. 10, 2015).*

action program requirements, would improve notice to sponsors that some sponsors are not subject to the affirmative action program requirements. Some apprenticeship programs are also qualifying Federal contractors that have developed AAPs under OFCCP's laws, and thus would not incur any additional burden to create and maintain AAPs under these regulations.

The proposed rule deletes the text in current § 30.4(c) which provides: ''The Department may provide such financial or other assistance as it deems necessary to implement the requirements of this paragraph,'' because the Department does not need a regulatory requirement in order to provide such assistance. Proposed § 30.5, outlined below, replaces the current § 30.4(e). The proposed rule also deletes current § 30.4(f) and addresses the establishment of utilization goals for race, sex, and ethnicity in proposed § 30.6 and for individuals with disabilities in proposed § 30.7.

Finally, the proposed regulation adds a new § 30.4(e) addressing the schedule for the review of affirmative action programs. Under the current regulations, a sponsor is required to complete an internal review of its affirmative action plan, which includes all the elements listed in the proposed § 30.4(c) set out above, on an annual basis. This NPRM incorporates that existing practice, but proposes an alternative schedule of review for those sponsors that can demonstrate their program is fully meeting the objectives set forth in this paragraph. Specifically, if a contractor's AAP demonstrates that it is not underutilized in any of the protected bases for which measurements are kept (race, sex, and disability) and that its review of personnel practices did not require any necessary modifications to meet nondiscrimination objectives, then the sponsor may wait two years to complete its next internal AAP review and update its written plan. This proposal is intended to provide an incentive to sponsors who have shown success in meeting their AAP and nondiscrimination obligations. We seek comments on this proposal, including specifically whether stakeholders believe such an approach would incentivize AAP success without compromising the overall goals of promoting and ensuring equal employment opportunity in registered apprenticeship.

Utilization Analysis for Race, Sex, and Ethnicity (§ 30.5)

The Department proposes revising the current § 30.5, entitled ''Selection of apprentices,'' and moving the revised language to § 30.10; the revised language is discussed later in the preamble at § 30.10. In its place, the Department proposes a new § 30.5, which provides guidelines for assessing whether possible barriers to apprenticeship exist for particular groups of individuals by determining whether the race, sex, and ethnicity of apprentices in a sponsor's apprenticeship program is reflective of the population available for apprenticeship by race, sex, and ethnicity in the sponsor's relevant recruitment area. Availability is the yardstick against which the actual utilization of individuals by race, sex, and ethnicity in the sponsor's apprenticeship program workforce is measured. Where a disparity exists between availability and the actual representation in the sponsor's apprenticeship program, the sponsor would be required to establish a utilization goal. The Department anticipates that grouping these provisions into one specific section that is clearly titled, ''Utilization Analysis for Race, Sex, and Ethnicity,'' rather than subsuming them in the current part 30 section on affirmative action, also would improve the regulation's overall organization and readability.

Proposed § 30.5 replaces current § 30.4(e), ''Analysis to determine if deficiencies exist,'' which requires the sponsor to compute availability separately for minorities and for women, for each particular occupation. The current part 30 requires the sponsor to consider at least the following five factors in determining availability: (1) The size of the working age minority and female population in the program sponsor's labor market area; (2) the size of the minority and female labor force in the program sponsor's labor market area; (3) the percentage of minority and female participation as apprentices in the particular craft, as compared with the percentage of minorities and women in the labor force in the program sponsor's labor market area; (4) the percentage of minority and female participation as journeyworkers employed by the employer or employers participating in the program, as compared with the percentage of minorities and women in the sponsor's labor market area, and the extent to which the sponsor should be expected to correct any deficiencies through the achievement of goals and timetables for the selection of apprentices; and (5) the general availability of minorities and women with present or potential capacity for apprenticeship in the program sponsor's labor market area.

Under the current part 30, although the sponsor must consider all five factors, it is not required to use each factor in determining the final availability estimate, and may consider other factors not listed in the regulation. Only the factors that are relevant to the actual availability of apprentices for the particular craft in question must be used under the current part 30. As a result, most sponsors actually use only a few of the five factors to compute the final availability estimates. Moreover, how these factors in the current part 30 relate to the availability of qualified individuals for apprenticeship is unclear. Finally, the current part 30 does not indicate how a sponsor should consider or weight each of these factors when determining availability.

Proposed § 30.5 describes the steps required to perform utilization analyses, and would simplify the availability computations by reducing the number of factors from five to two. In addition, proposed § 30.5 would require that a sponsor consider the availability of qualified individuals for apprenticeship by race, sex, and ethnicity, rather than continue the current approach, which requires the sponsor to analyze availability and utilization for women and then for minorities as an aggregate group.

As a first step in determining whether a particular group is being underutilized, proposed § 30.5(b) would require sponsors to identify the racial, sex, and ethnic composition of its apprentice workforce. Rather than review the composition for each occupational title represented in a sponsor's apprenticeship program, the proposed § 30.5(b) would simplify the analysis by requiring the sponsor to group the occupational titles represented in its registered apprenticeship program by industry. If a sponsor has programs in various occupations (*e.g.,* carpenter, electrician, glazier, maintenance technician), but these programs are all in one industry (*e.g.,* construction), then the sponsor conducts the utilization analysis based on that one industry. Grouping by industry permits aggregation of apprenticeable occupations that are sufficiently similar to permit meaningful analysis while being sufficiently refined to identify potential barriers. In addition, these industry groupings would minimize the administrative burden for sponsors performing the analyses, particularly for those sponsors who have apprenticeship

programs in which more than one occupational title is represented.

The next step in a sponsor's utilization analysis would be to determine the availability of qualified individuals for apprenticeship by race, sex, and ethnicity. Under proposed § 30.5(c), the following two factors would be considered in determining the availability of qualified individuals for apprenticeship:

(1) The percentage of individuals available in the sponsor's relevant recruitment area with the present or potential capacity for apprenticeship in each industry, broken down by race, sex, and ethnicity; and

(2) The percentage of the sponsor's current employees with the present or potential capacity for apprenticeship broken down by race, sex, and ethnicity.

That is, the sponsor is to examine two broad sets of people: (1) Their current employees who are not in an apprenticeship program, but who have the capacity to be in the apprenticeship program, and (2) the broader labor force in the relevant recruitment area who are qualified and available for apprenticeship.

To determine the availability percentages in proposed § 30.5(c), the benchmark to which the sponsor compares its apprenticeship program, the sponsor must use the most current and discrete statistical information available to derive availability figures by industry. Specifically, sponsors are asked to consult the Bureau of Labor Statistics' Occupational Handbook to review the educational background requirements for relevant occupations.

Examples of other publicly available data sources available for sponsors to use include, but are not limited to, data from the Census Bureau's American Community Survey EEO Tabulation 2006 to 2010 currently available at *http://www.census.gov/people/eeotabulation/data/eeotables20062010.html*; the Census Bureau's Census 2000 EEO Data Tool currently available at *http://www.census.gov/eeo2000/index.html*; the Census Bureau's Quick Facts tables currently available at *http://quickfacts.census.gov*; the Census Bureau's American Fact Finder currently available at *http://factfinder2.census.gov/faces/nav/jsf/pages/index.xhtml*; labor market information data from State workforce agencies; data from vocational education schools, secondary and post-secondary school or other career and employment training institutions; educational attainment data from the Census Bureau; and for sponsors of registered apprenticeship programs in the construction industry, any data provided by OFCCP through their regulations at 41 CFR part 60–4 or otherwise on the potential availability of workers by demographic group for employment in on-site construction occupations. ''Potential availability percentage'' means an availability estimate that reflects current employment in an on-site construction occupation and current employment in non-construction occupations that employ workers who have similar abilities and interests to the workers in the corresponding on-site construction occupation.

Proposed § 30.5(c)(4) would require a sponsor to define its recruitment area reasonably based on objective criteria and to document how the recruitment area was defined. Proposed § 30.5(c)(4) prohibits sponsors from drawing the relevant recruitment area in such a way as to have the effect of excluding individuals on the basis of race, sex, or ethnicity from consideration.

Finally, proposed § 30.5(d) would require a sponsor to establish a utilization goal in accordance with the procedures set forth in proposed § 30.6 when underutilization occurs. Underutilization is the difference between availability for apprenticeship in a given industry and incumbency (*i.e.,* the sponsor's apprentice workforce in that industry). In other words, the proposed rule would require a sponsor to establish a utilization goal when the sponsor's utilization of women, Hispanics or Latinos, and/or particular racial minority groups is less than would be expected given their availability for apprenticeship. Sponsors would be permitted to identify underutilization using a variety of methods, including the ''any difference'' rule, *i.e.,* whether any difference exists between the availability of individuals by race, sex, and ethnicity for apprenticeship in a given industry and the number of such persons actually employed as an apprentice in the industry; the ''one person'' rule, *i.e.,* whether the difference between availability and the actual employment of individuals as apprentices equals one person or more for a given race, sex, or ethnicity; the ''80 percent rule,'' *i.e.,* whether actual employment of apprentices, broken down by race, sex, and ethnicity, is less than 80 percent of their availability; and a ''two standard deviations'' analysis, *i.e.,* whether the difference between availability and the actual employment of apprentices by race, sex, and ethnicity exceeds the two standard deviations test of statistical significance. Proposed paragraph 30.5(d) clarifies that utilization goals are not required where no disparity in utilization rates for any particular group has been found.

The methodology in proposed § 30.5 would refine a sponsor's utilization analysis and would help pinpoint whether any particular group is being underutilized, which will in turn aid the sponsor in fashioning a more tailored affirmative action program for addressing the specific underutilization. The Department recognizes that the existence of and access to relevant data sources may vary depending on the sponsor's geographic location and the occupations included in its registered apprenticeship program. The Department has intentionally designed proposed § 30.5 and related provisions for goal-setting in proposed § 30.6 to provide a broad framework that has the flexibility to accommodate continuing upgrades and improvements in publicly-available data sources appropriate for conducting utilization analyses.

The Department also plans to provide significant technical assistance and sub-regulatory policy and program guidance to assist program sponsors and Registration Agencies to comply with the proposed § 30.5 and proposed § 30.6. We anticipate that such guidance will address, among other things, how best to analyze a sponsor's registered apprenticeship program workforce, including through the use of data aggregation from a range of years of program operations in order to identify a utilization rate that is most meaningful to sponsors, including those with small apprenticeship programs, and a utilization goal for race, sex, and ethnicity that is appropriate to the size and circumstances of each sponsor's program. The Department believes the issuance of examples and technical assistance in guidance documents maintains the flexibility necessary to accommodate the evolving data analysis tools and data sources used for availability analysis and goal-setting. The Department welcomes specific comments and suggestions from the public regarding what data and/or tools exist that would enable program sponsors to determine, within their relevant recruitment area, the availability of individuals with the present or potential capacity for apprenticeship broken down by race, sex, and ethnicity. Also, the Department requests comments specifically addressing what criteria, other than educational attainment, sponsors can use to help distinguish between those individuals in the relevant recruitment area with the present or potential capacity for apprenticeship and those in

the relevant recruitment area without such capacity.

Establishment of Utilization Goals for Race, Sex, and Ethnicity (§ 30.6)

The Department proposes to remove current § 30.6 entitled ''Existing list of eligibles,'' because the Department is proposing to change the approach to selection procedures. For a discussion of the proposed selection procedures, see proposed § 30.10 discussed later in the preamble.

Proposed § 30.6 describes the procedures for establishing utilization goals and would replace the existing procedures set forth in § 30.4(f) of the current part 30. Under the current § 30.4(f), a sponsor is required to establish goals and timetables based on the outcome of the sponsor's analyses of its underutilization of minorities in the aggregate and women. It is acceptable for a sponsor to develop a single goal for minorities and a separate single goal for women, unless a particular minority group is employed in a substantially disparate manner in which case separate goals are required for each group. In establishing goals, the sponsor is encouraged to consider the results which could reasonably be expected from its good faith efforts to make its overall affirmative action program work. The current part 30 does not provide specific instructions on how to set a goal nor does it explain what constitutes good faith efforts on the part of a sponsor. In addition, under the current part 30, the form of goal that a sponsor is required to set depends on the nature of the selection procedure used. For selections based on rank from a pool of eligible applicants, for instance, sponsors are required to establish a percentage goal and timetable for the admission of minority and/or female applicants into the eligibility pool. However, if selections are made from a pool of current employees, sponsors are required to establish goals and timetables for actual selection into the apprenticeship program.

The Department proposes several changes to the current goal setting approach. First, for simplification, the proposed rule would require that sponsors adopt just one type of goal regardless of the selection procedure used. Under proposed § 30.6, a sponsor would be required to establish a utilization goal for representation of the particular group in the sponsor's apprenticeship program. Second, proposed § 30.6 would remove any reference to timetables, because the proposed goal setting approach requires that sponsors evaluate annually (or every two years, if it meets the conditions in the proposed § 30.4(e)) whether goals are needed and make adjustments to their goals as needed. Third, proposed § 30.6 would add language explaining that quotas are expressly forbidden; goals may not be used to extend a preference to any individual on the basis of race, sex, or ethnicity; and goals may not be used to supersede eligibility requirements for apprenticeship. Fourth, proposed § 30.6 would clarify that the percentage goal must be at least equal to the availability figure that the sponsor computes. Currently, part 30 is silent as to how a sponsor must calculate its goal, other than to say sponsors must create a goal when underutilization has been found. Finally, to ensure a sponsor's affirmative action program is tailored to address the barriers to EEO it has identified, proposed § 30.6 would require that goals be set only for the particular racial or ethnic group(s) that the sponsor has identified as being underutilized, rather than for minorities in the aggregate.

Utilization Goals for Individuals With Disabilities (§ 30.7)

Current § 30.7 is reserved. In keeping with the proposed expanded scope of part 30 and of the affirmative action requirements, this proposed rule would assign a new section entitled ''Utilization goals for individuals with disabilities'' to § 30.7. In contrast to the framework set forth for establishing utilization goals for race, sex, and ethnicity, proposed § 30.7 would establish a single, national utilization goal of 7 percent for individuals with disabilities that applies to all sponsors subject to proposed § 30.4, Affirmative Action Programs. Proposed § 30.7(a) sets forth this goal.

Proposed § 30.7(b) states that the purpose of this section is to establish a benchmark against which the sponsor must measure the representation of individuals with disabilities in the sponsor's apprentice workforce by industry, in order to assess whether any barriers to EEO remain. The goal serves as an equal opportunity objective that should be attainable by complying with all of the affirmative action requirements of part 30.

Proposed § 30.7(c) provides that the Administrator of OA will periodically review and update, as appropriate, the utilization goal established in proposed § 30.7(a).

Proposed § 30.7(d) sets out the steps that the sponsor must use to determine whether it has met the utilization goal. Proposed § 30.7(d)(1) states that the purpose of the utilization analysis is to evaluate the representation of individuals with disabilities in the sponsor's apprentice workforce grouped by industry and compare the rate against the utilization goal set forth in proposed § 30.7(a). If individuals with disabilities are represented in the sponsor's apprentice workforce in a given industry at a rate less than the utilization goal, the sponsor must take specific measures to address this disparity.

Proposed § 30.7(d)(2) explains that the utilization analysis is a two-step process. First, the sponsor is required to group all occupational titles represented in its apprenticeship program by industry. As discussed above, if a sponsor has apprenticeship programs in various occupations (*e.g.,* carpenter, electrician, glazier, maintenance technician), but these programs are all in one industry (*e.g.,* construction), then the sponsor conducts the utilization analysis based on that one industry. Next, for each industry represented, the sponsor must identify the number of apprentices with disabilities based on voluntary self-identification by the individual apprentices. Proposed § 30.7(d)(3) requires that the sponsor evaluate its utilization of individuals with disabilities in each industry group annually (or every two years, if it meets the conditions set forth in the proposed § 30.4(e)).

When the percentage of apprentices with disabilities in one or more industry groups is less than the utilization goal proposed in § 30.7(a), proposed § 30.7(e) requires that the sponsor take steps to determine whether and where impediments to equal opportunity exist. Proposed § 30.7(e) explains that when making this determination, the sponsor must look at the results of its assessment of personnel processes and the effectiveness of its outreach and recruitment efforts as required by proposed § 30.9. If, in reviewing its personnel processes, the sponsor identifies any barriers to equal opportunity, then proposed § 30.7(f) requires that the sponsor undertake action oriented programs designed to correct any problem areas that the sponsor identified. Only if a problem or barrier to equal opportunity is identified, must the sponsor develop and execute an action-oriented program.

Proposed § 30.7(g) clarifies that the sponsor's determination that it has not attained the utilization goal in one or more industry groups does not constitute either a finding or admission of discrimination in violation of part 30. It is important to note, however, that such a determination, whether by the sponsor or by the Registration Agency, will not impede the Registration Agency

from finding that one or more unlawful discriminatory practices caused the sponsor's failure to meet the utilization goal. In such a circumstance, the Registration Agency will take appropriate enforcement measures.

Lastly, proposed § 30.7(h) states that the goal proposed in this section must not be used as a quota or ceiling that limits or restricts the employment of individuals with disabilities as apprentices.

The establishment of a utilization goal for individuals with disabilities would be a new requirement, which the Department believes is warranted in light of the long-term and intractable nature of the substantial employment disparity between those with and without disabilities. Little Government data measuring the unemployment and workforce participation rates of individuals with disabilities exists prior to the 2000 Census. However, illustrative data can be found in the 1989 legislative history of the ADA. Explaining the need for inclusion of employment provisions in the then-pending legislation, the Senate reported that individuals with disabilities ''experience staggering levels of unemployment.'' [28] More specifically, the Senate reported that two-thirds of all disabled Americans of working age were not working at all, even though a large majority of those not working (66 percent) wanted to work.[29]

Today, more than 20 years later, there continues to be a substantial discrepancy between the workforce participation and unemployment rates of working age [30] individuals with and without disabilities. As explained earlier in this preamble, both the unemployment rate and the percentage of working age individuals with disabilities who are not in the labor force remain significantly higher than that of the working age population without disabilities.

The establishment of a utilization goal for individuals with disabilities is not, by itself, a ''cure'' for this longstanding problem. We believe, however, that the goal proposed in this section is a vital element that, in conjunction with other requirements of this part, will enable sponsors and Registration Agencies to assess the effectiveness of specific affirmative action efforts with respect to individuals with disabilities, and to identify and address specific workplace barriers to employment as an apprentice.

This adoption of a single, national goal of 7 percent would establish consistency among the Department's regulations requiring covered entities to engage in nondiscrimination and affirmative action for qualified individuals with disabilities. The Department's OFCCP recently published a Final Rule implementing section 503 of the Rehabilitation Act of 1973 (section 503) which establishes for the first time a single, national utilization goal of 7 percent for individuals with disabilities for all covered contractors. 78 FR 58682, Sept. 24, 2013.

As detailed in that Final Rule, the OFCCP derived this utilization goal in part from the disability data collected as part of the American Community Survey (ACS). The ACS was designed to replace the census ''long form'' of the decennial census, last sent out to U.S. households in 2000, to gather information regarding the demographic, socioeconomic and housing characteristics of the nation. Whereas the Census Bureau now only administers a very short survey for the decennial census, a more detailed view of the social and demographic characteristics of the population is provided by the ACS, which collects data from a sample of 3 million residents on a continuing basis.[31]

The ACS was first launched in 2005, after a decade of testing and development by the Census Bureau. Refinement of the questions designed to characterize disability status has been continuous, with the current set of disability-related questions incorporated into the ACS in 2008. Taken together, the six dichotomous (''yes'' or ''no'') disability-related questions [32] comprise the function-based definition of ''disability,'' used in the ACS and by most of the other major surveys administered by the Federal Statistical System.

The definition of disability used by the ACS, however, is clearly not as broad as that in the ADA and proposed here. For example, since the ACS questions do not say that one should respond without considering mitigating measures (*e.g.,* medication or aids), some individuals with disabilities that are well-controlled by medication (*e.g.,* depression or epilepsy) or in remission might respond to the ACS in a way that leads them not to be coded as ''disabled.'' Likewise, since the ACS questions do not include major bodily functions, an individual who has a disability that substantially limits a major bodily function such as HIV, cancer, or diabetes but does not limit an activity such as hearing, seeing or walking, might respond that he or she does not have a disability on the ACS. Despite its limitations, the ACS is the best source of nationwide disability data available today, and, thus, an appropriate starting place for developing a utilization goal.

Consistent with OFCCP's approach set forth in its Final Rule implementing section 503, OA proposes to set a single, national goal for individuals with disabilities, based on the most recent 2009 ACS disability data for the ''civilian labor force'' and the ''civilian population,'' [33] first averaged by EEO–1 job category, and then averaged across EEO–1 category totals. Specifically, the Department used the mean across these EEO–1 groups (5.7 percent) as a starting point for deriving a range of values upon which we will take comment; 5.7 percent is the Department's estimate of the percentage of the civilian labor force that has a disability as defined by the ACS. However, the Department acknowledges that this number does not encompass all individuals with disabilities as defined under the broader definition in the ADA, as amended, and this part. Further, this figure most likely underestimates the percent of individuals with disabilities with the present or potential capacity for apprenticeship because it reflects the percentage of individuals with disabilities who are currently in the labor force with an occupation and individuals need not have an occupation or be in the labor force in order to be eligible for apprenticeship. Therefore, 5.7 percent should not be construed as an affirmative action goal for individuals with disabilities under these authorities, nor convey a false

[28] Senate Committee on Labor and Human Resources, S. Rep. No. 101–116, 101st Cong, 1st Sess. (1989) at 9.

[29] *Id.* (citing a poll by the Lou Harris company).

[30] The working age population consists of people between the ages of 16 and 64, excluding those in the military and people who are in institutions.

[31] A national sample of approximately 3 million addresses nationwide receives the ACS each year, with a portion of this total receiving the survey each month. For more information on the American Community Survey visit the Census Bureau's ACS Web page at *www.census.gov/acs.*

[32] The six questions are: Is this person deaf or does he/she have serious difficulty hearing? Is this person blind or does he/she have serious difficulty seeing even when wearing glasses? Because of a physical, mental, or emotional condition, does this person have serious difficulty concentrating, remembering, or making decisions? Does this person have serious difficulty walking or climbing stairs? Does this person have difficulty dressing or bathing? Because of a physical, mental, or emotional condition, does this person have difficulty doing errands alone such as visiting a doctor's office or shopping? 2009 American Community Survey, Questions 17–19.

[33] The civilian labor force is the sum of people who are employed and those who are unemployed and looking for work. The civilian population is the civilian labor force plus civilians who are not in the labor force, excluding those in institutions.

sense of precision. Even if the 5.7 percent represented a complete availability figure for all individuals with disabilities as defined under the ADA, we are concerned that such an availability figure does not take into account discouraged workers, or the effects of historical discrimination against individuals with disabilities that has suppressed the representation of such individuals in the workforce. Discouraged workers are those individuals who are not now seeking employment, but who might do so in the absence of discrimination or other employment barriers. There are undoubtedly some individuals with disabilities who, for a variety of reasons, would not seek employment even in the absence of employment barriers. However, given the acute disparity in the workforce participation rates of those with and without disabilities, it is reasonable to assume that at least a portion of that gap is due to a lack of equal employment opportunity.

One way to go about estimating the size of the discouraged worker effect would be to compare the percent of the civilian population with a disability (per the ACS definition) who identified as having an occupation to the percent of the civilian labor force with a disability who identified as having an occupation. Though not currently seeking employment, it might be reasonable to believe that those in the civilian population who identify as having an occupation, but who are not currently in the labor force, remained interested in working should job opportunities become available. Using the 2009 ACS EEO–1 category data, the result of this comparison is 1.7 percent. Again, we believe this figure underestimates the percentage of discouraged workers who may be eligible for apprenticeship because it measures who in the current population, *with an occupation,* may be discouraged from employment, and individuals eligible for apprenticeship need not have had an occupation at any time.[34]

Adding this figure to the 5.7 percent availability figure above results in the 7.4 percent.[35] OFCCP uses this level, rounded to 7 percent in its Final Rule to revise section 503 to avoid implying a false level of precision, as it is an initial approximation of the availability for employment of individuals with disabilities. OA adopts this approach in this proposed rule to revise part 30.

The Department recognizes that registered apprenticeship program sponsors who are subject to the utilization goal for individuals with disabilities (*i.e.,* those with five or more registered apprentices who are not otherwise exempt under proposed § 30.4(d)) often have programs that are quite small, some with less than twenty registered apprentices. The purpose of the utilization goal requirement is to encourage sponsors to be more aware of how effective their employment practices are in ensuring equal employment opportunity for individuals with disabilities.

Under this proposed rule, a sponsor who failed to meet the utilization goal for individuals with disabilities required in proposed § 30.7—for example, a sponsor with 14 apprentices, none of whom is an individual with a disability—would be required to determine whether and where impediments to equal opportunity exist, and if such problem areas are identified, to implement targeted outreach, recruitment, and retention activities to ensure that individuals with disabilities are, in fact, learning about registered apprenticeship opportunities. These targeted activities would be done in addition to the universal outreach and recruitment that is required of all sponsors and not in lieu of, with the end result being that the sponsor is, in fact, reaching the broadest pool of applicants and apprentices. In contrast, if the same sponsor with 14 apprentices had one or more apprentices with a disability, the sponsor would achieve the proposed utilization goal for individuals with disabilities, and would not be required to engage in targeted outreach, recruitment, and retention activities for individuals with disabilities. Instead, the sponsor would simply be required to continue to engage in universal outreach and recruitment that is required under § 30.3(b)(3) of this part.

The Department recognizes that many sponsors of registered apprenticeship programs and Registration Agencies will require assistance with implementing proposed § 30.7. We plan, therefore, to provide significant technical assistance and sub-regulatory policy and program guidance that will address, among other things, how best to analyze a sponsor's registered apprenticeship program workforce, including through the use of data aggregation from a range of years of program operations, in order to identify a utilization rate that is most meaningful to the sponsor; how to ensure equal employment opportunity through best practices; and how to ensure a work environment inclusive of individuals with disabilities.

The Department welcomes specific comments and suggestions from the public regarding what data and/or tools exist that would enable program sponsors to determine, within their relevant recruitment area, the availability of individuals with disabilities with the present or potential capacity for apprenticeship, recognizing that individuals need not be in the current labor force to be eligible for apprenticeship. In addition, the Department invites public comment on the methodology used to calculate the utilization goal for individuals with disabilities and whether there might be other approaches for setting a utilization goal, particularly approaches to setting ranges that recognize that in some geographic areas and for some occupations, there may be fewer people with disabilities qualified and eligible for apprenticeship. The Department also seeks comment on whether and, if so, how to take into account discouraged workers in assessing the availability of individuals with disabilities for registered apprenticeship. The Department is also very interested in public comment on whether there are empirically-based approaches that recognize that there are many more people who have disabilities as characterized by the ADA than the ACS and that there is likely a discouraged worker effect.

The Department further invites public comment on the impact of this proposal on sponsors, and on the impact a fixed goal would have on sponsors of smaller apprenticeship programs who are required to establish an affirmative action program and comply with the utilization goal requirement for individuals with disabilities.

Targeted Outreach, Recruitment, and retention (§ 30.8)

The Department proposes to revise current § 30.8 entitled ''Records'' and to move that language to proposed § 30.11, as discussed later in the preamble. Proposed § 30.8 instead would replace the current requirements related to outreach and positive recruitment discussed in § 30.4(c) of the current part 30 by addressing the regulatory requirements related to targeted outreach, recruitment, and retention.

Under proposed § 30.8, where a sponsor has made a finding of underutilization and established a utilization goal for a specific group or groups pursuant to proposed § 30.6,

[34] This number was derived from an updated 2009 version of Table 24 in *Affirmative Action for People with Disabilities—Volume I: Data Sources and Models,* Economic Systems, Inc. (April 30, 2010) at 64. The original table uses ACS data from 2008.

[35] As it is derived from ACS data, the 1.7 percent is also a limited number that does not fully encompass all individuals with disabilities as defined in the ADA and this NPRM.

and/or where a sponsor has determined, pursuant to proposed § 30.7(f), that there are problem areas with respect to its outreach, recruitment, and retention activities for individuals with disabilities, the sponsor must undertake targeted outreach, recruitment, and retention activities that are likely to generate an increase in applications for apprenticeship and improve retention of apprentices from the targeted group or groups and/or from individuals with disabilities as appropriate. These targeted activities would be in addition to the sponsor's universal outreach and recruitment activities that now would be required under proposed § 30.3(b)(3). As discussed earlier in the preamble to the proposed rule, these proposed universal outreach and recruitment activities require development of a list of recruitment sources and notification of these sources at least 30 days in advance of any apprenticeship opportunities, whereas proposed § 30.8 sets forth four broad categories of minimum, specific activities required to address underutilization. These four categories are discussed below.

The Department specifically mentions retention activities in proposed § 30.8 to highlight that a sponsor's retention efforts are an important part of the EEO regulatory framework for the National Registered Apprenticeship System. The Department does not require program sponsors to retain an apprentice who does not demonstrate sufficient progress in his or her apprenticeship simply because the individual is from the specific group or groups. The Department would incorporate retention activities in proposed § 30.8 to emphasize that the requirements for EEO in registered apprenticeship extend to the entire term of apprenticeship, not just to the recruitment and selection of apprentices. By including retention activities in proposed § 30.8, the Department further emphasizes that all apprentices should receive fair and equitable treatment regardless of race, sex, ethnicity, or disability so that each can progress through a full term of apprenticeship.

Finally, the Department does not expect the specific mention of retention activities in proposed § 30.8 to increase a sponsor's burden of complying with this rule. Rather, these retention activities are representative of the kinds of good faith efforts the Department has required to date for a sponsor to meet its EEO obligations required in §§ 30.3 and 30.4 of the current part 30, such as use of journeyworkers to assist with affirmative action efforts; establishing pre-apprenticeship programs to prepare candidates for apprenticeship; cooperating with local schools and vocational education systems to develop programs to prepare students for entry into apprenticeship programs; and education and outreach to the education and workforce systems to raise awareness about apprenticeship opportunities.

Proposed § 30.8(a)(1) would set forth the minimum, specific targeted outreach, recruitment, and retention activities required of a sponsor that has found underutilization of a particular group or groups pursuant to § 30.6 and/or who has determined pursuant to § 30.7(f) that there are problem areas with respect to its outreach, recruitment, and retention activities. These activities include, but need not be limited to: (1) Dissemination of information to community-based organizations, local high schools, local community colleges, local vocational, career and technical schools, career centers at minority serving institutions (including Historically Black Colleges and Universities, Hispanic-Serving Institutions, and Tribal Colleges and Universities), and other groups serving the underutilized group; (2) advertising openings for apprenticeship opportunities by publishing advertisements in newspapers and other media, electronic or otherwise, that have wide-spread circulation in the relevant recruitment area; (3) cooperating with local school boards and vocational education systems to develop and/or establish relationships with pre-apprenticeship programs inclusive of students from the underutilized groups, preparing them to meet the standards and criteria required to qualify for entry into apprenticeship programs; and (4) establishing linkage agreements enlisting the assistance and support of pre-apprenticeship programs, community-based organizations and advocacy organizations in recruiting qualified individuals for apprenticeship and in developing pre-apprenticeship programs. We believe that these four activities should be attainable for all programs but request comment on whether there are any exceptional circumstances under which it might be difficult to complete them.

Consistent with a recommendation from the ACA to align requirements for outreach and recruitment activities with established national best practices, the Department conducted a literature review and examined technical assistance tools and materials issued by various stakeholders in the National Registered Apprenticeship System, including SAAs, advocacy organizations, and program sponsors. In the Department's experience with the grant projects authorized by Women Apprenticeship Nontraditional Occupations (WANTO),[36] and in the reports and materials from career and technical education organizations,[37] the California Apprenticeship Council,[38] and research and advocacy organizations focusing on women,[39] [40] these outreach activities have proven key in assisting sponsors to recruit female and minority applicants for apprenticeship who may not have otherwise learned about apprenticeship opportunities, and in retaining them once they are enrolled in registered apprenticeship. Given the usefulness of these specific activities, we also believe they provide the most efficient way for sponsors to meaningfully address underutilization. Such activities, including linkage agreements, need not be highly formal, detailed arrangements, but rather are intended to be straightforward, dynamic partnerships that can be easily tailored to meet sponsors' needs. Therefore, the Department proposes these types of activities to support program sponsors' efforts to meet utilization goals established under proposed §§ 30.6(a) and 30.7(e). Additionally, the Department welcomes specific comments and suggestions from the public regarding what specific employment practices have been

[36] Information about WANTO grants is available on-line: *http://www.dol.gov/wb/programs/family2.htm*; *http://www.dol.gov/wb/03awards.htm*; and *http://www.dol.gov/opa/media/press/wb/wb20100817.htm*.

[37] *Programs and Practices That Work: Preparing Student for Nontraditional Careers Project,* Joint project sponsored by the Association of Career and Technical Education, the National Alliance for Partnerships in Equity, the National Association of State Directors of Career Technical Education Consortium, and the National Women's Law Center (Washington DC 2006).

[38] California Apprenticeship Council, Blue Ribbon Committee on Women in Apprenticeship Final Report and Recommendations (California 2006).

[39] *See, e.g.,* Brown, J.K., and Jacobsohn, F., ''From the Ground Up: Building Opportunities for Women in Construction.'' Legal Momentum, New York, NY, (2008); Skidmore, E., and Moir, S., ''Designing a Pre-apprenticeship Model for Women Entering and Succeeding in The Construction Trades: A Report to YouthBuild Providence,'' (September 2004); and Moir, S., Thomson, M., and Kelleher, C., ''Unfinished Business: Building Equality for Women in the Construction Trades,'' *Labor Resource Center Publications* (April 2011): Paper 5.

[40] *See, e.g.,* Port Jobs, ''Building the Foundation: Opportunities and Challenges Facing Women in Construction in Washington State,'' Study prepared through a contract with Apprenticeship and Nontraditional Employment for Women and Men with funding support from the Workforce Development Council of Seattle-King County, (Seattle, WA November 2006), and Hard Hatted Women, ''A Toolkit for the Recruitment and Retention of Women,'' funded by a WANTO grant from the U.S. Department of Labor (Cleveland, OH 2009).

verifiably effective in recruiting, hiring, advancing, and retaining women, minorities, and individuals with disabilities in registered apprenticeship.

In terms of conducting both universal outreach and recruitment required under proposed § 30.3(b), and targeted outreach and recruitment for individuals with disabilities that might be required under proposed § 30.8, the Department would recommend program sponsors contact the following types of organizations: State Vocational Rehabilitation Agencies, the State Workforce System (including State Workforce Investment Boards, Local Workforce Investment Boards, and One-Stop Career Centers), Centers for Independent Living, Goodwill and other community rehabilitation and employment service providers, Community College Disability Centers, Community College Career Centers, Alternative Schools, Community Mental Health programs, and the Social Security Administration's Employment Networks.

In addition, to foster awareness of the usefulness of a sponsor's outreach, recruitment, and retention activities, proposed § 30.8(a) would also require the sponsor to evaluate and document the overall effectiveness of its outreach, recruitment, and retention activities after every selection cycle for registering apprentices. While the proposal does not specify the precise contents of this evaluation, OA expects that it would include at a minimum the criteria used to evaluate the effectiveness of each activity and the sponsor's subsequent conclusion as to its effectiveness. This review will allow the sponsor to refine these activities as needed, as set forth in the proposed § 30.8(a)(3). Finally, the proposal requires the sponsor to maintain records of its outreach, recruitment, and retention activities and any evaluation of these activities (§ 30.8(a)(4)). This approach is designed to help sponsors identify barriers to apprenticeship, prevent discrimination, and ensure equal opportunity for all.

In addition to the activities required in § 30.8(a), as a matter of best practice, proposed § 30.8(b) encourages but does not require sponsors to consider other outreach, recruitment, and retention activities that may assist them in addressing any barriers to equal opportunity in apprenticeship. Such activities include but are not limited to: (1) Use of journeyworkers and apprentices from the underutilized group or groups to assist in the implementation of the sponsor's affirmative action program; (2) use of individuals from the underutilized group or groups to serve as mentors and to assist with the sponsor's targeted outreach and recruitment activities; and (3) conducting exit interviews of each apprentice leaving the sponsor's apprenticeship program prior to receiving his/her certificate of completion to understand better why the apprentice is leaving and to help shape the sponsor's retention activities.

Review of Personnel Processes (§ 30.9)

The Department proposes to revise and rename the current § 30.9 entitled ''Compliance reviews,'' and to move that language to § 30.12, as discussed below in the preamble.

Proposed § 30.9 requires that any sponsor who is subject to the affirmative action program requirements in this proposed rule (*i.e.,* those with five or more apprentices who are not otherwise exempt) must review its personnel processes on at least an annual basis to ensure that it is meeting its obligations under part 30, unless it qualifies for a bi-annual review as set forth in § 30.4(e), in which case the review would take place every two years. As part of this review, proposed § 30.9 would require that the sponsor review all aspects of its apprenticeship program, including but not limited to the qualifications for apprenticeship, wages, outreach and recruitment activities, advancement opportunities, promotions, work assignments, job performance, rotations among all work processes of the occupation, disciplinary actions, handling of requests for reasonable accommodations, and the program's accessibility to individuals with disabilities (including accessibility of information and communication technology) and make all necessary modifications to ensure compliance with the equal opportunity obligations of this part. Essentially, this review is simply a good business practice that most employers should already be doing as a matter of course—examining the personnel decisions they make to ensure that they are free from unlawful discrimination. Such a review ultimately inures to the benefit of the employer, as, done appropriately, it can ferret out potential discrimination proactively, rather than in response to employee complaints and litigation and their attendant costs. Proposed § 30.9 would also require a sponsor to include a description of its review in its written AAP, and to identify in the plan any modifications that the sponsor has made or plans to make as a result of this review. In conjunction with this NPRM, OA will post on its Web site specific examples of what a successful review of personnel processes would entail, how it could be completed most efficiently, and how these steps could be easily documented in the written AAP.

This proposed requirement is similar to one set forth in the current part 30 at § 30.4(c)(10), which suggests that a sponsor audit periodically its affirmative action program and activities to ensure that its employment activities with respect to recruitment, selection, employment, and training of apprentices is without discrimination because of race, color, religion, national origin, and sex. Proposed § 30.9 emphasizes the philosophy the Department intends to convey throughout the regulation that affirmative action is not only a requirement on paper, but also a dynamic part of the sponsor's management approach, requiring ongoing monitoring, reporting, and revising to address barriers to EEO and to ensure that discrimination does not occur. Sponsors are required to create and sustain affirmative action programs that incorporate: (1) Proactive measures designed to actively welcome all qualified individuals, including women, minorities, and individuals with disabilities, to participate in registered apprenticeship; (2) thorough, systematic efforts to prevent discrimination from occurring; and (3) methods to detect and eliminate discrimination. The Department requests comments specifically addressing how to ensure that these reviews remain a dynamic part of the management approach that is effective in preventing, ferreting out, and correcting any discrimination in employment. The Department is also interested in receiving comments on whether it would be beneficial to involve apprentices and journeyworkers in the review.

Selection of Apprentices (§ 30.10)

The Department proposes to revise current § 30.10 entitled ''Noncompliance with Federal and [S]tate equal opportunity requirements,'' and to move that language to § 30.3(b)(5), as discussed above.

As described earlier in this preamble, under the current § 30.5, sponsors may select any one of four methods of selecting apprentices: (1) Selection on the basis of rank from pool of eligible applicants; (2) random selection from pool of eligible applicants; (3) selection from pool of current employees; or (4) an alternative selection method which allows the sponsor to select apprentices by means of any other method including its present selection method, subject to approval by the Registration Agency. An alternative selection method could be, for example, the use of interviews as one of the factors to be considered in

selecting apprentices. Another alternative method could use pre-apprenticeship programs as a source of candidates. A sponsor also may combine two or more selection methods.

One common method that sponsors have used regularly, which would fall under this fourth category, is referred to as ''direct entry.'' Under this selection method, the application process would be waived so that qualified applicants can enter directly into an apprenticeship program, where the individual applicant demonstrates specific education and/or skills previously attained. In order for sponsors to use ''direct entry,'' this method must be defined clearly in the selection procedure component of the sponsor's apprenticeship standards, and must be approved by the Registration Agency. Provisions for ''direct entry'' in an apprenticeship program sponsor's registered standards enable the development of formal relationships between an apprentice sponsor and other organizations or entities that prepare individuals to meet the sponsor's requirements for selection into apprenticeship. Examples of organizations for which many apprenticeship program sponsors may have ''direct entry'' provisions in their apprenticeship standards include graduates from Job Corps Centers and YouthBuild sites; as well as veterans participating in the AFL–CIO Building and Construction Trades Department's ''Helmets to Hard Hats'' or the United Association of Journeymen and Apprentice of the Plumbing and Pipe Fitting Industry of the United States and Canada (UA)'s Veterans in Piping (VIP) Program.

Proposed § 30.10 would simplify the regulatory requirements related to selection procedures by allowing a sponsor to adopt *any* method for selection of apprentices, including direct entry, provided that the method used: (1) Complies with the UGESP at 41 CFR part 60–3; (2) is uniformly and consistently applied to all applicants for apprenticeship and apprentices; (3) complies with the qualification standards set forth in title I of the ADA; and (4) is facially neutral in terms of race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, and disability. The Department believes this approach would greatly simplify the regulatory structure currently governing selection procedures and would distill the current requirements to their essence. This proposed approach for selection procedures also would be consistent with how other equal opportunity laws regulate an employer's use of selection procedures.

Invitation To Self-Identify as an Individual With a Disability (§ 30.11)

The Department proposes to revise current § 30.11 entitled ''Complaint procedure,'' and to move that language to § 30.14, as discussed later in the preamble.

This section of the proposed rule is new and proposes to require sponsors, as part of their general duty to engage in affirmative action, to invite applicants for apprenticeship to voluntarily self-identify as an individual with a disability protected by this part at three stages: (1) At the time they apply or are considered for apprenticeship; (2) after they are accepted into the apprenticeship program but before they begin their apprenticeship; and (3) once they are enrolled in the program. Thereafter, proposed § 30.11 would require sponsors to remind apprentices yearly that they may voluntarily update their disability status, thereby allowing those who have subsequently become disabled or who did not wish to self-identify during the application and enrollment process to be counted.

The purpose of this section is to collect important data pertaining to the participation of individuals with disabilities in the sponsor's applicant pools and apprenticeship program. This data will allow the sponsor and OA to better identify and monitor the sponsor's enrollment and selection practices with respect to individuals with disabilities. Data related to the pre-offer stage will be particularly helpful, as it will provide the sponsor and OA with valuable information regarding the number of individuals with disabilities who apply for apprenticeship with sponsors. This data will enable OA and the sponsor to assess the effectiveness of the sponsor's recruitment efforts over time, and to refine and improve the sponsor's recruitment strategies, where necessary. In addition, data from the application stage, post-offer, will allow sponsors and OA to assess the impact selection procedures and qualification standards may have on individuals with disabilities. And finally, data related to apprentices once they are in the program will help sponsors assess whether there may be barriers to equal opportunity in all aspects of apprenticeship and may inform the effectiveness of retention strategies or whether such strategies are necessary.

Proposed § 30.11(a)(1) requires that the sponsor invite each applicant to voluntarily self-identify as an individual with a disability whenever the applicant applies for or is considered for apprenticeship. The invitation may be included with the application materials, but must be separable or detachable from the application for apprenticeship.

The requirement to give applicants and employees the opportunity to self-identify is consistent with the ADA. Although the ADA generally prohibits inquiries about disability prior to an offer of employment, it does not prohibit the collection of this information by a sponsor in furtherance of its part 30 affirmative action obligation to provide equal opportunity in apprenticeship for qualified individuals with disabilities.[41] The EEOC's regulations implementing the ADA state that the ADA ''does not invalidate or limit the remedies, rights, and procedures of any Federal law . . . that provides greater or equal protection for the rights of individuals with disabilities'' than does the ADA. 29 CFR 1630.1(c)(2). The OA part 30 rule is one such law.

Proposed § 30.11(a)(2) requires that the sponsor invite applicants to self-identify ''using the language and manner prescribed by the Administrator and published on the OA Web site.'' This requirement will ensure consistency in all pre-offer invitations that are made, and will reassure applicants that the request is routine and executed pursuant to obligations created by OA. It will also minimize any burden on sponsors resulting from compliance with this responsibility as they will not be required to develop suitable self-identification invitations individually. This, in turn, we believe, will facilitate sponsor compliance with this proposed section.

The inquiry that OA will prescribe for sponsors is a limited one and will be narrowly tailored. To minimize privacy concerns and the possibility of misuse of disability-related information, the Department is proposing that the required invitation ask only for self-identification as to the existence of a ''disability,'' not as to the general nature or type of disability the individual has, or the nature or severity of any limitations the individual has a result of their disability. Below is the language

[41] This issue was addressed in the course of OFCCP's rulemaking revising its Section 503 regulations to, among other things: Include a pre-offer disability self-identification requirement. The EEOC's Office of Legal Counsel issued a letter stating that the Section 503 self-identification requirement was lawful under the ADA; the legal rationale in that letter would apply with equal force to the self-identification requirement in this proposal as well. A copy of the letter is available at *http://www.dol.gov/ofccp/regs/compliance/sec503/Self_ID_Forms/OLC_letter_to_OFCCP_8-8-2013_508c.pdf* (last accessed Sept. 8, 2015).

OA proposes to prescribe that the sponsor use when inviting applicants to self-identify at the pre-offer stage. To ensure consistency across Departmental programs, the language is modeled on the invitation to self-identify that Federal contractors are required to use when complying with the requirements of section 503, but is adapted for use in the Registered Apprenticeship context. In all other respects, it is identical to what OFCCP requires of Federal contractors under section 503:

1.*Why are you being asked to complete this form?* Because we are a sponsor of a registered apprenticeship program and participate in the National Registered Apprenticeship System that is regulated by the U.S. Department of Labor, we must reach out to, enroll, and provide equal opportunity in apprenticeship to qualified people with disabilities.[42] To help us measure how well we are doing, we are asking you to tell us if you have a disability or if you ever had a disability. Completing this form is voluntary, but we hope that you will choose to fill it out. If you are applying for apprenticeship, any answer you give will be kept private and will not be used against you in any way.

If you already are an apprentice within our registered apprenticeship program, your answer will not be used against you in any way. Because a person may become disabled at any time, we are required to ask all of our apprentices at the time of enrollment, and then remind them yearly, that they may update their information. You may voluntarily self-identify as having a disability on this form without fear of any punishment because you did not identify as having a disability earlier.

2. *How do I know if I have a disability?* You are considered to have a disability if you have a physical or mental impairment or medical condition that substantially limits a major life activity, or if you have a history or record of such an impairment or medical condition.

Disabilities include, but are not limited to: Blindness, deafness, cancer, diabetes, epilepsy, autism, cerebral palsy, HIV/AIDS, schizophrenia, muscular dystrophy, bipolar disorder, major depression, multiple sclerosis (MS), missing limbs or partially missing limbs, post-traumatic stress disorder (PTSD), obsessive compulsive disorder, impairments requiring the use of a wheelchair, intellectual disability (previously called mental retardation).

Please check one of the boxes below:

☐ YES, I HAVE A DISABILITY (or previously had a disability)

☐ NO, I DON'T HAVE A DISABILITY

☐ I DON'T WISH TO ANSWER

Your name:

Date:

OA invites public comment on this potential self-identification text and whether there are any reasons, programmatic or otherwise, as to why OA should not adopt a similar form to the one used by OFCCP and covered Federal contractors.

Proposed § 30.11(b)(1) requires that the sponsor invite applicants, after acceptance into the apprenticeship program, but before they begin their apprenticeship, to voluntarily self-identify as individuals with disabilities. The Department proposes to include a post-offer invitation to self-identify requirement, in addition to the invitation at the pre-offer stage, so that individuals with hidden disabilities who fear potential discrimination if their disability is revealed prior to being accepted into the program will, nevertheless, have the opportunity to provide this valuable data.

Proposed § 30.11(b)(2) requires that the sponsor invite self-identification using the language and manner prescribed by the Administrator and published on the OA Web site. Again, the Department believes that this requirement will ensure consistency in all post-offer invitations that are made, minimize any burden to sponsors of compliance with this responsibility, and consequently, facilitate such sponsor compliance.

Proposed § 30.11(c) requires that the sponsor invite each of its apprentices to voluntarily self-identify as an individual with a disability at the time the sponsor becomes subject to the requirements of part 30 and then remind apprentices yearly that they may update their disability status at any time. Allowing apprentices enrolled in a registered apprenticeship program to update their status will ensure that the sponsor has the most accurate data possible.

Proposed § 30.11(d) emphasizes that the sponsor is prohibited from compelling or coercing individuals to self-identify. While proposed § 30.11(e) emphasizes that all information regarding self-identification as an individual with a disability shall be kept confidential and maintained in a data analysis file in accordance with proposed § 30.12. Proposed § 30.11(e) also states that self-identification must be provided to the Registration Agency upon request and that the information may only be used in accordance with this part.

Proposed § 30.11(f) states that nothing in this section may relieve the sponsor of its obligation to take affirmative action with respect to those applicants and apprentices of whose disability the sponsor has knowledge.

Finally, proposed § 30.11(g) clarifies that nothing in this proposed section may relieve the sponsor from liability for discrimination in violation of this part.

Recordkeeping (§ 30.12)

The Department proposes to remove current § 30.12 entitled ''Adjustments in schedule for compliance review or complaint processing'' because the information contained within this section has been incorporated into the proposed sections addressing EEO compliance reviews and complaints.

Proposed § 30.12 prescribes the recordkeeping requirements that would apply to registered apprenticeship program sponsors, and concludes that a sponsor's failure to comply with these requirements would constitute noncompliance with the part 30 regulations. Proposed § 30.12 retains, in large part, the recordkeeping requirements currently in § 30.8, subject to basic editing, and updates them to reflect the development and use of electronic recordkeeping, and the broadened scope of the proposed rule to provide for equal opportunity, affirmative action, and nondiscrimination for applicants and apprentices with disabilities.[43] Proposed § 30.12, therefore, includes a new provision regarding the confidentiality and use of medical information that is obtained pursuant to part 30, including information regarding whether an applicant or apprentice is an individual with a disability. Proposed § 30.12(e) provides that any information collected that concerns the medical condition or history of an applicant or apprentice must be maintained in separate forms and in separate medical files and treated as confidential. Furthermore, proposed § 30.12(e) makes clear that any information obtained by a sponsor regarding the medical condition or history of any applicant or apprentice must not be used for any purpose inconsistent with part 30.

In addition, proposed § 30.12 would remove any reference to the recordkeeping requirements of State

[42] Section 503 of the Rehabilitation Act of 1973, as amended. For more information about this form or the equal employment obligations of Federal contractors, visit the U.S. Department of Labor's Office of Federal Contract Compliance Programs (OFCCP) Web site at *www.dol.gov/ofccp*.

PUBLIC BURDEN STATEMENT: According to the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. This survey should take about 5 minutes to complete.

[43] OA maintains guidance that provides more explanation on exactly what documents must be maintained, and how sponsors should maintain it. *See* Bulletin 2010–11a Apprenticeship Program Standards Section XVIII Maintenance of Records and Appendix D, Section VI Maintenance of Records *http://www.doleta.gov/OA/bul10/Bulletin%202010-11%20Revised%20Boilerplates.pdf.* (last accessed September 10, 2015). In addition, OA will provide publicly available materials in conjunction with this NPRM that will update this guidance consistent with this proposal.

Apprenticeship Councils. The Department proposes to move these requirements to proposed § 30.18, the section addressing SAAs. This proposed change would ensure that all requirements specific to SAAs can be found in one location.

Finally, proposed § 30.12(d) would decrease the amount of time that sponsors are required to keep documentation from five to three years. This decreases the amount of data contractors must store while maintaining the general purposes of allowing sponsors and OA the ability to review previous records for necessary information.

Equal Employment Opportunity Compliance Reviews (§ 30.13)

The Department proposes to revise current § 30.13 entitled ''Sanctions'', re-title the section ''Enforcement actions,'' and move the revised language to § 30.15, as discussed later in this preamble.

Proposed § 30.13 would carry forward the current provision at § 30.9 addressing compliance reviews and would include several modifications to improve readability. In addition to improving the readability of the rule and ensuring uniformity in compliance reviews, proposed § 30.13 is intended to convey the Department's strong commitment to supporting apprenticeship program sponsors' compliance with OA's EEO regulations through the compliance review process.

First, proposed § 30.13 would revise the title from ''Compliance reviews'' to ''Equal employment opportunity compliance reviews,'' clarifying that the reviews are to assess compliance with part 30 and not the companion regulations at part 29. Second, the term ''Registration Agency'' would be used throughout proposed § 30.13 instead of the term ''Department,'' because this section applies to both the Department and to SAAs when conducting an EEO compliance review. Third, proposed § 30.13 would provide more specificity for the procedures Registration Agencies must follow in conducting compliance reviews.

This increased specificity would provide for greater consistency and standardization of procedures across the National Registered Apprenticeship System. For instance, proposed § 30.13(b) would require the Registration Agency to notify a sponsor of the Agency's findings through a written Notice of Compliance Review Findings within 45 business days of completing a compliance review. The Notice of Compliance Review Findings must include whether any deficiencies (*i.e.,* failures to comply with the regulatory requirements) were found, how they are to be remedied, and the time frame within which the deficiencies must be corrected. The Notice of Compliance Review Findings also must notify a sponsor that sanctions may be imposed for failing to correct deficiencies. The current part 30 at § 30.9(d) simply states that the Department must notify the sponsor in writing of its results from a compliance review.

Finally, proposed § 30.13(c) addresses what is expected of sponsors who receive a Notice of Compliance Review Findings indicating a failure to comply with the part 30 regulations. Specifically, proposed § 30.13(c) requires that a sponsor implement a compliance action plan within 30 business days of receiving the Notice of Compliance Review Findings and notify the Registration Agency of that action. The compliance action plan must contain a specific written, action-oriented program that demonstrates a commitment to correct or remediate the identified deficiencies. The compliance action plan also must set forth the specific actions the sponsor plans to take, and must indicate the time period within which the corrections will be taken. Specifically, the compliance action plan would need to include information such as who is the responsible party for the action, what action will be taken, how the action would be implemented, and the time period within which the action would be implemented or completed. A sponsor that fails to implement its compliance action plan would be subject to enforcement action under proposed § 30.15.

Complaints (§ 30.14)

The Department proposes to revise current § 30.14 entitled ''Reinstatement of program registration'' and to move that language to § 30.16, as discussed later in the preamble.

Section 30.11 of the current part 30 addresses the procedures for filing and processing complaints. The proposed rule would move individual complaint procedures to proposed § 30.14, and would include additional revisions to improve readability and clarify requirements of program sponsors and Registration Agencies for addressing complaints. For instance, proposed § 30.14 would incorporate subheadings so that an apprentice or applicant for apprenticeship who wishes to file a complaint of discrimination under this part with a Registration Agency may easily identify the required components. Specifically, proposed § 30.14(a)(1) through (3) describe who has standing to file a complaint, the time period for filing a complaint, and the required contents of the complaint.

Proposed § 30.14 would delete the provisions concerning private review bodies in the current part 30, at § 30.11(a) and (b). Through feedback from the SAAs, stakeholders at the town hall meetings, and the administration of the National Registered Apprenticeship System, the Department has found that apprenticeship program sponsors generally do not have or use private review bodies. Additionally, stakeholders expressed the opinions that such bodies could not objectively evaluate or prescribe remedies for complaints of discrimination. Thus, the proposed rule would eliminate the use of private review bodies.

Proposed § 30.14(b) requires sponsors to provide notice to all applicants for apprenticeship and apprentices of their right to file a discrimination complaint with the Registration Agency and the procedures for doing so. Proposed § 30.14(b) also specifies the required wording for this notice. A sponsor may combine this notice and its equal opportunity pledge in a single posting for the purposes of this proposed section and proposed § 30.3(b)(2)(ii).

Also, in an effort to ensure consistency in how Registration Agencies process complaints and conduct investigations, proposed § 30.14(c) would add uniform procedures that Registration Agencies must follow. These uniform procedures would ensure that: The Registration Agency acknowledges and thoroughly investigates complaints in a timely manner; parties are notified of the Registration Agency's findings; and the Registration Agency attempts to resolve complaints quickly through voluntary compliance.

Proposed § 30.14(c)(3) provides that a Registration Agency may, at any time, refer a complaint to an appropriate EEO enforcement agency. This provision would allow Registration Agencies to safeguard the welfare of apprentices by making use of existing Federal and State resources and authority. For example, a Registration Agency might refer a complaint to the EEOC if it finds a violation of title VII, the ADA, or the ADEA, but does not think it could achieve a complete remedy for the complainant through voluntary compliance procedures or enforcement action under proposed § 30.15. Additionally, ETA plans to develop a Memorandum of Understanding with the EEOC, which will describe the complaint processing and referral procedures between the two agencies in

more detail. This coordination will further the purpose of Executive Order 12067, by helping to eliminate duplicative and/or conflicting investigations or compliance reviews. 43 FR 28967, June 30, 1978.

Proposed § 30.14(c)(4) would allow a SAA to adopt slightly different complaint procedures, but only if it submits the proposed procedures to OA and receives OA's approval. This provision would codify the Department's current practice and would be consistent with § 29.12(f) of this title.

Enforcement Actions (§ 30.15)

The Department proposes to revise current § 30.15 entitled ''State Apprenticeship Councils'' and to move that language to § 30.18, as discussed later in the preamble.

Section 30.13 of the current part 30, entitled ''Sanctions,'' states that when the Department has reasonable cause to believe that an apprenticeship program is not operating in accordance with part 30, and where the sponsor fails to voluntarily take corrective action, the Department will initiate deregistration proceedings or refer the matter to the EEOC or the United States Attorney General with a recommendation for initiation of a court action. The rest of the section describes the procedures for deregistration proceedings.

Proposed § 30.15 would make several revisions to the requirements that are outlined in the current § 30.13. First, proposed § 30.15 would be entitled ''Enforcement actions'' to demonstrate the Department's emphasis on enforcing regulations governing discrimination in the workplace. Second, as a housekeeping measure, the term ''Department'' would be replaced throughout proposed § 30.15 with the term ''Registration Agency'' to clarify that both the Department (more specifically, OA) and SAAs have the authority to take enforcement action against a non-complying sponsor.

Third, proposed § 30.15(b) would introduce a new enforcement procedure in which a Registration Agency would suspend registration of new apprentices until the sponsor has achieved compliance with part 30 through the completion of a compliance action plan or until a final order is issued in formal deregistration proceedings. In the Department's experience, many sponsors have found it beneficial to have cohorts or groups of apprentices enter and start their apprenticeship at different times so that at any given point, the sponsor may have first, second, third, and fourth year apprentices, rather than one cohort of apprentices scheduled to complete their apprenticeship at the same time. These sponsors have been more willing to remedy violations when they find that they will be unable to register new apprentices until they have demonstrated compliance with part 30, including the remedying of any discrimination. Expanding the range of enforcement actions to include this suspension option is also consistent with a recurring theme for stricter enforcement of EEO obligations raised by stakeholders in OA's listening sessions and in consultations with stakeholders in Spring 2010, as discussed above in the overview of the NPRM. Suspension is intended as a temporary, remedial measure to spur return to compliance with the proposed part 30 regulations; it is not intended to be punitive. If a sponsor has not taken the necessary corrective action within 30 days of receiving notice of suspension, the Registration Agency will initiate de-registration proceedings as provided in part 29.

Fourth, proposed § 30.15(c) would adopt the deregistration procedures of §§ 29.8(b)(5) through (8) of this title, including the hearing procedures in § 29.10, for consistency and simplicity. This revision would allow SAAs to follow a single set of procedures for all matters arising from management of the National Registered Apprenticeship System.

Finally, proposed § 30.15(d) would authorize Registration Agencies to refer a matter involving a potential violation of equal opportunity laws to appropriate Federal or State EEO agencies, whether the Registration Agency becomes aware of the potential violation through a complaint investigation, compliance review, or other means.

Reinstatement of Program Registration (§ 30.16)

Current § 30.16 entitled ''Hearings'' would be removed. As explained earlier in the preamble, the Department proposes to incorporate the part 29 procedures for hearings into part 30, so that a sponsor need only follow one set of procedures regardless of whether the issue at hand addresses the labor standards set forth in part 29 or the equal opportunity standards set forth in part 30. Current § 30.14 states that any apprenticeship program that has been deregistered pursuant to part 30 may be reinstated by the Secretary, upon presentation of adequate evidence that the program is operating in accordance with part 30. Proposed § 30.16 would be revised to align with part 29, which provides that requests for reinstatement must be filed with and decided by the Registration Agency.

These proposed revisions, which are consistent with §§ 29.8, 29.9, 29.10 and 29.13 of this title, implement Secretary's Order 1–2002, 67 FR 64272, Oct. 17, 2002.[44] Accordingly, the proposal provides that requests for reinstatement must be filed with and decided by the Registration Agency.

Intimidation and Retaliation Prohibited (§ 30.17)

The Department proposes to revise the title of the current § 30.17 from ''Intimidatory or retaliatory acts'' to ''Intimidation and retaliation prohibited,'' as well as to make other stylistic changes to improve the readability of the rule. In addition, proposed § 30.17 would expand the bases upon which a sponsor must not intimidate or retaliate in order to protect more fully the rights of apprentices.

The current § 30.17 states that a sponsor must not intimidate, threaten, coerce, or retaliate against any person for the purpose of interfering with any right or privilege secured by title VII or Executive Order 11246. Proposed § 30.17 revises this language by stating that sponsors would be prohibited from intimidating or retaliating against any individual because he or she has opposed a practice prohibited by this part or any other Federal or State equal opportunity law or participated in any manner in any investigation, compliance review, proceeding, or hearing under part 30 or any Federal or State equal opportunity law.

State Apprenticeship Agencies (§ 30.18)

The Department proposes to revise current § 30.18 entitled ''Nondiscrimination,'' which states that the commitments contained in a sponsor's affirmative action programs must not be used to discriminate against an apprentice or applicant for apprenticeship on the basis of race, color, religion, national origin, and sex, and to incorporate those revisions into proposed § 30.4, as discussed earlier in the preamble.

Proposed § 30.18 revises current § 30.15, which requires State Apprenticeship Councils to adopt State plans. These proposed revisions are necessary to make proposed part 30 consistent with the part 29 procedures for recognition of SAAs.

[44] Secretary's Order 1–2002 delegated authority and assigned responsibility to the Administrative Review Board to act for the Secretary of Labor in review or appeal of decisions and recommended decisions by Administrative Law Judges as provided for or pursuant to National Apprenticeship Act, 29 U.S.C. 50; 29 CFR parts 29 and 30.

Proposed § 30.18 differs significantly from the current § 30.15, because proposed § 30.18 does not include State Apprenticeship Councils as entities eligible for recognition. As provided in § 29.13 of this title, the Department will only recognize an SAA that complies with the specified requirements, granting that agency authority to register apprenticeship programs and apprentices for Federal purposes. Therefore, proposed § 30.18 would delete references to ''State Apprenticeship Councils'' as the entities required to submit a State EEO plan and the entities eligible for recognition, and replace it with the appropriate term, ''State Apprenticeship Agency.''

Proposed § 30.18(a) sets forth requirements for a State EEO plan. The proposed rule would require, within one year of the effective date of the final rule, with no extensions permitted, that SAAs provide to OA a State EEO plan that includes the State apprenticeship law that corresponds to the requirements of this part and requires all apprenticeship programs registered with the State for Federal purposes to comply with the requirements of the State's EEO Plan within 180 days from the date that OA provides written approval of the State EEO plan. The Department's determination of compliance with this part is separate from submission of the State EEO plan. Therefore, proposed § 30.18(a) also specifies a collaborative, iterative process whereby SAAs seeking recognition can achieve conformity with this part. Proposed § 30.18(a) also would provide clarity regarding requirements for demonstration of conformity, while maintaining flexibility to accommodate the unique circumstances of a particular SAA.

Proposed § 30.18(b) carries forward existing recordkeeping requirements at current § 30.8(d), using the term ''State Apprenticeship Agency'' instead of ''State Apprenticeship Council.'' Proposed § 30.18(c) also carries forward provisions in § 30.15(a)(4), which state that OA retains full authority to conduct EEO compliance reviews of apprenticeship programs, investigate complaints, deregister for Federal purposes an apprenticeship program registered with a recognized SAA, and refer any matter pertaining to these EEO compliance reviews or these complaints to the EEOC, the U.S. Attorney General, or the Department's OFCCP. In addition, proposed § 30.18(c) clarifies that OA retains authority to conduct complaint investigations to determine whether any program sponsor registered for Federal purposes is operating in accordance with this part.

Proposed § 30.18(d) clarifies that SAAs will be subject to the derecognition procedures established in § 29.14 of this title, for failure to comply with the requirements of this part.

Exemptions (§ 30.19)

Section 30.19 of the current rule addresses exemptions. Under current § 30.19, a sponsor may submit a written request to the Secretary for an exemption from part 30, or any part thereof, and such a request may be granted by the Secretary for good cause. State Apprenticeship Councils are required to notify the Department of any such exemptions granted that affect a substantial number of employers and the reasons therefore.

The Department proposes minor revisions to this section. First, proposed § 30.19 requires that requests for exemption be submitted to the Administrator, rather than the Secretary, to reflect a shift in Departmental decision-making. Second, proposed § 30.19 requires that SAAs, not State Apprenticeship Councils, request and receive approval from the Administrator to grant an exemption from these regulations. As discussed above, State Apprenticeship Councils are not eligible for recognition under § 29.13 of this title. This proposed regulatory requirement is to ensure consistency with respect to when exemptions may be granted.

Effective Date (§ 30.20)

Proposed § 30.20 is a new section. It provides the dates by which all apprenticeship programs registered with a Registration Agency must comply with this part. Proposed § 30.20(a) would require all apprenticeship program sponsors to amend its Standards of Apprenticeship to include the equal opportunity pledge prescribed by § 30.3(c), and to comply with the non-discrimination requirements prescribed by § 30.3(a).

Proposed § 30.20(b) and 30.20(c) set forth the deadlines by which sponsors must comply with their affirmative action program related obligations. Section 30.20(b) addresses deadlines for sponsors and potential sponsors in states with State Apprenticeship Agencies, and paragraph (c) addresses deadlines in states without SAAs, in which sponsors register directly with OA. The deadlines for each are slightly different because upon publication of the final regulation, SAAs must amend their EEO plans and OA must approve that amendment. The deadlines for each must also take into account whether a program is new or existing as of the time the final regulation would go into effect.

As such, proposed § 30.20(b) addressing SAA states provides that sponsors with programs that are existing as of the effective date must adopt an AAP that complies with these regulations, and submit it to the SAA for approval, within 180 days after OA approves of the state's EEO plan revised in light of these regulations. While we cannot say for sure how long the state EEO plan revision and approval process will take, it will likely take at least several months, and perhaps a year or longer. For programs registered with an SAA after the effective date, the deadline will be the same up until the point that the state has approved the State's EEO plan. If a program is registered after the State's EEO plan has been approved, that program will have one year from registration to adopt a compliant AAP and submit it for approval. The intent is that this will provide ample time for all sponsors to understand and comply with their AAP obligations. As stated previously in this preamble, the Registration Agencies will provide technical assistance during this time to any sponsor seeking advice or clarification on the creation, drafting, and submission of its written plan.

The deadlines in § 30.20(c) are somewhat simpler given that sponsors registering directly with OA do not have to wait for a revised state EEO plan from an SAA. Accordingly, § 30.20(c) provides that, for programs existing as of the effective date of the final rule, they have one year from that effective date to adopt a compliant AAP. For programs that are registered after the effective date of the final rule, they have one year from registration to adopt and comply with the AAP obligations. Again, this should provide ample time for new and existing sponsors to understand the new obligations and receive any technical assistance from OA they might need to aid in the creation and submission of the written plan.

Finally, to repeat a point made in the discussion of § 30.4, the submission of the written plan to the Registration Agency is not an annual obligation; after the first plan under these proposed regulations, sponsors need only submit their current written plan to OA upon request. Thus, while sponsors will generally need to maintain and update their written AAPs annually for internal purposes (or potentially every two years, if the conditions in § 30.4(e), discussed below, are met), reviews will be less frequent.

Proposed Amendments to Part 29 Regulations, Labor Standards for Registration of Apprenticeship Programs

The part 29 regulations governing Labor Standards for Registration of Apprenticeship Programs include references to sections in part 30 that are changed through this proposed rule. This NPRM would make these technical, non-substantive changes for consistency and conformity with the proposed changes to part 30.

Section 29.5(b)(21), ''Standards of Apprenticeship,'' would incorporate three revisions. First, the reference to an equal opportunity pledge required by part 30 would be revised by deleting the reference to § 30.3(b) and replacing it with an updated reference to § 30.3(c). Second, the reference to the part 30 section on selection of apprentices would be revised by deleting the reference to § 30.5, where this reference sits in current part 30, and replacing it with a reference to § 30.10, where this reference now would sit under this NPRM. Third, the reference to requirements in § 30.4 would use the updated term ''affirmative action program'' in place of current term ''affirmative action plan.''

This NPRM would institute procedures to deregister programs in accordance with the deregistration proceedings of § 29.8(b)(5) through (8), and would delete separate proceedings for deregistration proceedings for violations of part 30. Therefore, the final sentence in § 29.8(b)(1)(i), which refers to processing of deregistration proceedings for violations of equal opportunity requirements in accordance with 29 CFR part 30, would be deleted.

This NPRM also would require procedures for deregistration of SAAs established in part 29 regulations, rather than maintaining separate procedures under the part 30. The reference to part 30 would be deleted from § 29.14(a).

Additionally, this NPRM proposes three substantive changes to § 29.7, which sets the requirements for apprenticeship agreements. An apprenticeship agreement, as defined in § 29.2, is the written agreement between an apprentice and either the apprentice's program sponsor or committee acting as agent for the program sponsor(s), which contains the terms and conditions of the employment and training of the apprentice. Consistent with nondiscrimination based on age (40 or older), genetic information, sexual orientation, or disability proposed in § 30.3(a), the proposed changes to § 29.7(j) would add age (40 or older), genetic information, sexual orientation, and disability to the list of protected bases for which the apprentice will be accorded equal opportunity in all phases of the apprenticeship employment and training without discrimination. Proposed additions to § 29.7 also update the apprenticeship agreement to accommodate recordkeeping requirements in proposed § 30.12(b), in which the sponsor must be able to identify the race, ethnicity, and when known, disability status, of each apprentice. Proposed § 29.7(l) would add space on the agreement in which an apprentice would voluntarily provide information about his or her race, sex, ethnicity, and disability status.

III. Regulatory Procedures

Executive Order 12866

Under Executive Order 12866, the Office of Information and Regulatory Affairs must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive Order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments, or communities in a material way (also referred to as an ''economically significant'' rule); (2) create serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The Department has determined that this NPRM is not an economically significant regulatory action under paragraph 3(f)(1) of Executive Order 12866. This rulemaking would not adversely affect the economy or any sector thereof, productivity, competition, jobs, the environment, or public health or safety in a material way. In fact, this NPRM is being proposed to increase the effectiveness and efficiency of EEO compliance within apprenticeship programs and to reduce the burden imposed on sponsors in several respects. The Department, however, has determined that this NPRM is a significant regulatory action under paragraph 3(f)(4) of the Executive Order and, accordingly, OMB has reviewed this NPRM.

1. Need for Regulation

As explained in the preamble, the Department is proposing to update the equal opportunity regulations that implement the National Apprenticeship Act of 1937. These regulations set forth at part 30 prohibit discrimination in apprenticeship on the basis of race, color, religion, national origin, and sex, and require that sponsors take affirmative action to provide equal opportunity in such programs. This NPRM proposes to update the part 30 regulations by including age (40 or older), genetic information, sexual orientation, and disability among the list of protected bases upon which a sponsor must not discriminate, and by detailing mandatory actions a sponsor must take to satisfy its affirmative action obligations.

In part, the Department is proposing this update so that the part 30 regulations align with 2008 revisions made to the Department's other set of regulations governing the National Registered Apprenticeship System at part 29. In addition, the part 30 regulations have not been amended since 1978 and EEO law has evolved since that time. The changes proposed in this NPRM are to ensure that the National Registered Apprenticeship System is consistent and in alignment with EEO laws as they have developed over the past 30 years, as discussed in Section I of the NPRM, and to ensure that apprentices and applicants for apprenticeship receive equal opportunity in apprenticeship programs.

The Department is concerned that women, Blacks or African Americans, Hispanics or Latinos, other racial minorities, individuals with disabilities, and older workers (40 or older) continue to face substantial barriers to equal opportunity in apprenticeship. Accordingly, a principal goal for this NPRM is to strengthen the EEO for the National Registered Apprenticeship System, and improve the effectiveness of an apprenticeship program sponsor's required affirmative action efforts, as well as improve sponsors' compliance with part 30. To achieve this goal, the Department has proposed the following changes to part 30:

(1) Updating the equal opportunity standards to include age (40 or older), genetic information, sexual orientation, and disability to the list of protected bases upon which sponsors of registered apprenticeship programs must not discriminate;

(2) Requiring all sponsors, regardless of size, to take certain affirmative steps to provide equal opportunity in apprenticeship;

(3) Streamlining the utilization analysis required of sponsors with five or more apprentices to determine whether any barriers to apprenticeship exist for individuals based on race, sex, or ethnicity, and clarifying when and how utilization goals are to be established;

(5) Requiring targeted outreach, recruitment, and retention activities when underutilization of a protected group or groups have been found and a utilization goal established per § 30.6 and/or where a sponsor has determined pursuant to § 30.7(f) that problem areas exist with respect to its outreach, recruitment, and retention activities for individuals with disabilities;

(6) Simplifying procedures for selecting apprentices;

(7) Standardizing procedures Registration Agencies [45] must follow for conducting compliance reviews;

(8) Clarifying requirements of program sponsors and Registration Agencies for addressing complaints;

(9) Adopting 29 CFR part 29 procedures for deregistration of SAAs, derecognition of apprenticeship programs, and hearings; and

(10) Requiring an invitation to self-identify as an individual with a disability.

These provisions are proposed to ensure that all individuals, including women, minorities, and individuals with disabilities, are afforded equal opportunity in registered apprenticeship programs. Moreover, the addition of age (40 or older), genetic information, sexual orientation, and disability to the list of those bases upon which a sponsor must not discriminate ensures that the National Registered Apprenticeship System's regulatory framework affords the same protections to individuals with disabilities and those 40 or older as it does for other protected groups, and the addition of these protected bases, including genetic information and sexual orientation, will bring the National Registered Apprenticeship System into alignment with the protected bases identified in the various Federal laws applicable to most apprenticeship sponsors. The Department's interest in updating part 30 to improve the effectiveness of sponsors' affirmative action efforts, as well as Registration Agencies' efforts to enforce and support compliance with this rule, lies in assuring that the Department's approval of a sponsor's apprenticeship program does not serve to support, endorse, or perpetuate private discrimination.

2. Economic Analysis

The Department derives benefit and cost estimates by comparing the baseline (the program benefits and costs under the 1978 Final Rule [46]) with the benefits and costs of implementing the provisions proposed in this NPRM. Only the additional benefits and costs that would be incurred due to the changes in this proposed regulation are included in the analysis. The Department requests comments on this analysis, including potential sources of data or information on the costs and benefits of the provisions in this proposed rule.

The Department sought to quantify and monetize the benefits and costs of this NPRM where feasible. Where we were unable to quantify benefits and costs—for example, due to data limitations—we describe them qualitatively. The analysis covers a 10-year period (2015 through 2024) to ensure it captures major benefits and costs that accrue over time. In this analysis, we have sought to present benefits and costs both undiscounted and discounted at 7 and 3 percent, respectively, following OMB guidelines.[47]

The 10-year monetized costs of this NPRM range from $109.61 million to $134.98 million (with 7 and 3 percent discounting, respectively). The 10-year monetized benefits of this NPRM range from $4.21 million to $5.28 million (with 7 and 3 percent discounting, respectively). The annual average costs of this NPRM range from $10.96 million to $13.49 million (with 7 and 3 percent discounting, respectively). The annual average benefits of this NPRM range from $0.42 million to 0.53 million (with 7 and 3 percent discounting, respectively).

In addition, we expect this NPRM to result in several overarching benefits to apprenticeship programs as well as some specific benefits resulting from a clearer, more systematic rule. As discussed below, equal opportunity policies may lead to both efficiency gains and distributional impacts to society. The proposed rule may reduce barriers to entry in apprenticeship programs for women, minorities, and persons with disabilities, fostering a distributional effect, and may alleviate the inefficiencies in the job market these barriers potentially create.

In the remaining sections, we first present the overall benefits of the proposed rule, followed by a subject-by-subject analysis of the benefits and costs. We then present a summary of the costs and benefits of this NPRM, including total costs over the 10-year analysis period. Finally, we conclude with a benefit-cost analysis of five alternatives (including the proposed rule).

a. Potential Overall Benefits and Distributional Effects of the Proposed Rule

This subsection presents the potential economic benefits and distributional effects of policy interventions related to equal opportunity employment. Claims about these impacts are derived from an extensive body of empirical labor market research published over the last two decades in peer-reviewed publications. We assume that similar effects would be attributable to this rule's combination of proposed provisions, not necessarily to a single provision. Some additional benefits associated with specific provisions of the rule are presented in the next section.

This NPRM proposes to clarify and improve the regulations on equal opportunity employment from the 1978 Final Rule by encouraging better recruiting and hiring practices. These enhanced affirmative action policies may lead to both efficiency effects and distributional effects. OMB Circular A–4 directs the consideration of both the efficiency and distributional effects of regulations.[48]

Job market efficiencies and other efficiency gains from affirmative action policies have been found to result from improvements of human resource functions. Human resource functions become more formal and more systematic, while incorporating impartial screening practices.[49] Firms subject to these types of policies tend to provide training and contribute to a more qualified workforce.[50] A policy that utilizes an outreach program resulting in more recruits raises the competition for job openings and thus

[45] As explained in Section I of the NPRM, part 29 prescribes procedures concerning the recognition of State Apprenticeship Agencies as Registration Agencies that can then register, cancel, and deregister apprenticeship programs within that State with the same authority as the Department and in accordance with the policies and procedures in part 29.

[46] 43 FR 20760, May 12, 1978 (requiring the inclusion of female apprentices in AAPs).

[47] OMB Circular No. A–4, ''Regulatory Analysis,'' M–03–21 (Sept. 2003).

[48] OMB Circular No. A–4, p. 14.

[49] Holzer, H. and Neumark, D., ''Assessing Affirmative Action,'' *Journal of Economic Literature,* Vol. XXXVII (2000).

[50] *Id.*

increases efficiency by employing the highest qualified individuals. A study by Schotter and Weigelt (1992) showed that equal opportunity policies increase the efforts of all workers, not just the underutilized workers.[51] The proposed rule may reduce barriers to entry in apprenticeship programs for women, minorities, and persons with disabilities, and may alleviate the inefficiencies in the job market that these barriers potentially create.

Without more specific affirmative action policies, women and minorities may have fewer job opportunities or invest in less education and training.[52] If underrepresented groups believe that certain jobs are unattainable, they may have little incentive to invest in training. Personal education and training investments not only help the individual but may have positive externalities in the long run because they can be mentors for future apprentices from underrepresented groups.[53] When more individuals invest in training and education in the short run, productivity and efficiency are likely to increase in labor markets over the long run.

In addition to its effect on efficiency, the proposed rule would result in a distributional effect. The direct beneficiaries of this proposed rule would be underrepresented workers: Women, minorities, and persons with disabilities. According to Holzer and Neumark (2000), ''affirmative action policies offer significant redistribution towards women and minorities, with relatively small efficiency consequences.'' [54]

Although true for all low income populations, evidence indicates that women are more likely to be classified as working poor and that Blacks or African Americans and Hispanics or Latinos are more than twice as likely as their Caucasian counterparts to be among the working poor.[55] In addition, persons with disabilities are almost three times more likely to live in poverty than other groups.[56] Construction, the largest represented industry sector in the National Registered Apprenticeship System, offers a higher median wage than traditionally female-dominated jobs and other jobs that do not require a college education for advancement, thus providing opportunity to move out of poverty or working poor status.[57]

To estimate the number of people with disabilities who will be affected by this proposed rule, we first obtained estimates of the prevalence of disabilities among workers in different industries. This tabulation gives the industry hiring rates for people with disabilities. Next, we assume that in a given industry, the apprenticeship programs enroll people with disabilities at the same rate as the industry hiring rate. Exhibit 1 shows these rates for 18–64 working age populations between 2008 and 2012. We see, for example that in Construction, 5.4 percent of all workers have a disability. Assuming that employers enroll new apprentices with disabilities at the same rate as they fire people with disabilities, this implies that the current prevalence of Construction apprentices with disabilities is also 5.4 percent. The utilization goal for individuals with disabilities set forth in the proposed rule is 7 percent of enrollees, so this means that 1.6 percent of enrollees (7 percent goal minus the 5.4 percent currently enrolled) would be enrolled who otherwise would not be. Since the number of new apprentices in 10 year span in Construction is projected by ETA to be $\times$ 660,718, this means that the proposed rule requiring a 7% enrollment rate will result in $(.07 - .054) \times 660{,}718 = 10{,}373$ more people with disabilities as new apprentices.[58]

This calculation, when repeated over all industries, gives a total estimate of an additional 22,080 individuals with disabilities who will be enrolled out of the total of 1,293,772 new apprentices projected over the next 10 years (2015–2024).

EXHIBIT 1—POTENTIAL IMPACT ESTIMATES

Industry	Industry hiring rate (%)	Projected new apprentices	Target (7%-current) (%)	Projected new apprentices with disabilities
Administrative-Support	5.5	5,708	1.5	86
Agriculture	6.2	1,813	0.8	14
Construction	5.4	660,718	1.6	10,373
Education	4.3	154,521	2.7	4,172
Oil, Gas, Mineral Extraction	5.7	636	1.3	8
Finance	3.9	521	3.1	16
Information	4.8	2,430	2.2	53
Medical Services	5.1	21,045	1.9	398
Manufacturing	5.3	146,950	1.7	2,439
Professional	4.8	2,617	2.2	58
Retail	5.9	11,339	1.2	130
Personal Service & Care	8.7	1,890	−1.7	−33
Service	6.0	7,135	1.0	73
Transportation	6.2	152,924	0.8	1,223
Utilities	4.5	114,982	2.5	2,886

[51] Schotter, A., and Weigelt, K., ''Asymmetric Tournaments, Equal Opportunity Laws and Affirmative Action: Some Experimental Results,'' *The Quarterly Journal of Economics,* (May 1992).

[52] Holzer, H. and Neumark, D., ''Assessing Affirmative Action,'' *Journal of Economic Literature,* Vol. XXXVII (2000).

[53] Dabke, S.; Salem, O.; Genaidy, A., et al. ''Job Satisfaction of Women in Construction Trades,'' *Journal of Construction Engineering and Management,* (March 2008).

[54] Holzer, H. and Neumark, D., ''Assessing Affirmative Action,'' *Journal of Economic Literature,* Vol. XXXVII (2000).

[55] *See* ''A Profile of the Working Poor, 2008'' Report 1022, published by BLS annually, for a breakdown of the working poor.

[56] World Institute on Disability, *http://www.wid.org/about-wid.*

[57] Median weekly earnings in construction are $611. For some women-dominated occupations, such as receptionists, hairdressers, and child care workers, the median weekly earnings are significantly lower: $480, $409, and $360, respectively. Source: U.S. Census Bureau, 2006 American Community Survey.

[58] We note here that ETA projections use growth rates between 5 percent and 20% for all industries. This is an estimated growth rate that would be required to meet or exceed the goal of doubling the number of apprentices. We believe this is highly unrealistic, because BLS employment projection 10-year average growth rates are between −1.1 percent and 2.6 percent. In many industries, notably Public Service, Agriculture, Forestry, Fishing, Hunting, Advanced manufacturing, Information and telecommunications, the growth rates are negative, meaning these industries are losing workers. When the 10-year average growth rate is used, the projected number of new apprentices becomes considerably smaller.

EXHIBIT 1—POTENTIAL IMPACT ESTIMATES—Continued

Industry	Industry hiring rate (%)	Projected new apprentices	Target (7%-current) (%)	Projected new apprentices with disabilities
Wholesale	4.9	8,543	2.1	180
Total		1,293,772		22,080

Source: OASP Tabulations, November 2014, ACS 2008–2012.

As noted above, the Department seeks specific comments on all aspects of the economic analysis presented here. In particular, the Department encourages the public to provide possible sources of data on the efficiency and distributional effects of the proposed rule, including the monetary gains from employing and retaining underrepresented groups, and the extent to which human resource and labor market functions are impacted by affirmative action policies.

3. Subject-by-Subject Analysis

The Department's analysis below considers the expected benefits (beyond those discussed above) and costs of the proposed changes to part 30. The analysis below considers the impacts of each proposed change to part 30 separately.

a. Familiarization With the Rule

To estimate the cost of rule familiarization, we multiplied the number of apprenticeship sponsors by the amount of time required to read the new rule (ranging from 2 to 6 hours, depending on how familiar the program sponsor is with the current part 30 requirements) and by the average hourly compensation of a private-sector human resources manager ($68.55).[59] In the first year of the rule, the cost to sponsors amounts to approximately $6.3 million in labor costs, for an average annual cost of $1.34 million over the 10-year analysis period.[60]

b. Addition of Age (40 or Older), Genetic Information, Sexual Orientation, and Disability to the List of Protected Bases

This NPRM would update the EEO standards to include age (40 or older), genetic information, sexual orientation, and disability to the list of protected bases upon which sponsors of registered apprenticeship programs must not discriminate (proposed § 30.3(a)). As explained in the preamble above, the addition of these bases to the types of discrimination prohibited by part 30 should not result in significant additional burden to sponsors as many of the National Registered Apprenticeship System's sponsors must already comply with Federal, State, and local laws and regulations prohibiting or otherwise discouraging discrimination against applicants and employees based on age (40 or older), genetic information, sexual orientation, and disability. Even among those sponsors not covered by such laws, many have internal EEO policies that prohibit discrimination on these bases. Therefore, the Department does not expect that the addition of age (40 or older), genetic information, sexual orientation, and disability to the list of protected bases in proposed §§ 30.1(a) and 30.3(a) would result in significant burdens to sponsors. The Department requests data or information on the percentage and type of sponsors, if any, who are not currently required to comply with the ADEA, GINA, Executive Order 11246 as amended by Executive Order 13672, the Americans with Disabilities Act, section 503 of the Rehabilitation Act, or any other law prohibiting discrimination against individuals on the basis of age (40 or older), genetic information, sexual orientation, or disability.

c. Specific Affirmative Steps To Provide Equal Opportunity

The proposed rule would require all sponsors, regardless of size, to take certain affirmative steps to provide equal opportunity in apprenticeship. Proposed § 30.3(b) would, for the first time, obligate sponsors to take the following basic steps to ensure EEO in apprenticeship.

First, sponsors would be required to designate an individual to be responsible and accountable for overseeing the sponsor's commitment to EEO (proposed § 30.3(b)(1)). The Department expects the burden of this requirement on sponsors to be minimal. Our understanding is that most, if not all, sponsors have an apprenticeship coordinator who is in charge of the apprenticeship program. The Department anticipates that this proposed requirement would be fulfilled by individuals currently providing coordination and administrative oversight functions for the program sponsor. We expect that the designation will be a relatively minor administrative matter, but one that will result in institutionalizing a sponsor's commitment to equal opportunity.

Second, the proposed rule would require for the first time that sponsors post their equal opportunity pledge on bulletin boards, including through electronic media, such that it is accessible to all apprentices and applicants to apprenticeship programs (proposed § 30.3(b)(2)). The cost of this proposed requirement is expected to be minimal. The Department assumes that it would take a sponsor 5 minutes (0.08 hours) to post the pledge and that this task would be performed by an administrative assistant at an hourly compensation rate of $22.28.[61] We multiplied the time estimate for this provision by the hourly compensation rate to obtain a total labor cost per sponsor of $1.84 ($22.28 × 0.08). However, updating the EO pledge to include age (40 or older), genetic information, sexual orientation, and disability will not create any new burden because it is already covered by the existing requirements.

To estimate the materials cost, the Department assumed that the pledge is

[59] We calculated the hourly compensation rate for a human resource manager by multiplying the median hourly wage of $47.94 (as published by the Department's OES survey, O*NET Online) by 1.43 to account for private-sector employee benefits (source: BLS). The hourly compensation rate for a human resource manager is thus $68.55 ($47.94 × 1.43).

[60] To calculate the labor burden, we multiplied the time to complete the task by the hourly compensation rate for sponsors ($68.55 × 4 = $274.2). The total cost for sponsors in 2015 is the labor cost multiplied by the total number of sponsors (23,014), or $6.3 million ($274.2 × 23,014). This burden occurs in the first year of the analysis period for existing sponsors, and every year thereafter only for new sponsors.

[61] We calculated the hourly compensation rate for an administrative assistant by multiplying the median hourly wage of $15.58 (as published by the Department's OES survey, O*NET Online) by 1.43 to account for private-sector employee benefits (source: BLS). Thus, the hourly compensation rate for an administrative assistant is $22.28 ($15.58 × 1.43).

one page, and that the cost per page for photocopying is $0.15, resulting in a materials cost of $0.15 ($0.15 × 1) per sponsor. Summing the labor and materials costs and multiplying this sum by the total number of sponsors in the first year results in a cost of $46,009 for this provision for the first year and an average annual cost of $73,939 over the 10-year analysis period.[62] The posting of the equal opportunity pledge is a one-time cost; costs after the initial year only occur for new sponsors.

Proposed § 30.3(b)(2) also requires each sponsor to conduct orientation and periodic information sessions for apprentices and journeyworkers who directly supervise apprentices, and other individuals connected with the administration or operation of the sponsor's apprenticeship program to inform and remind such individuals of the sponsor's equal employment opportunity policy with regard to apprenticeship. The orientation and information sessions required by proposed § 30.3(b)(2)(iii) underscore the sponsor's commitment to equal opportunity and its affirmation action obligations. These sessions would also institutionalize a sponsor's EEO policies and practices, providing a mechanism by which the sponsor may inform everyone connected with the apprenticeship program of the sponsor's obligations under part 30, and ensure that all individuals involved in the program understand these obligations and the policies instituted to implement them.

The Department first estimated that some of the 23,014 sponsors in the first year (2015) will hold one 30-minute regular orientation and periodic information session with on average 5 apprentices ($18.59)[63] and 5 journeyworkers ($36.47).[64] The Department estimated that a human resource manager ($68.55) would need to spend 4 hours to develop and prepare written materials for the session in the first year ($1.58 million = 23,014 sponsors × 4 hours × $68.55 × 25 percent). The Department also estimated that approximately 25 percent of the 23,014 sponsors would need to incur additional costs to comply with this provision. Most sponsors have already implemented this provision and would not incur any additional cost. This calculation results in a total cost for this provision of approximately $2.57 million in the first year (2015). The average annual cost over the 10-year analysis period is $1.44 million.

Third, under the current § 30.4(c) sponsors with 5 or more apprentices are required to engage in appropriate outreach and recruitment activities to organizations that serve women and minorities, and the regulations list the types of appropriate activities a sponsor is expected to undertake. The exact mix of activities depends on the size and type of the program and its resources, however each sponsor is ''required to undertake a significant number of appropriate activities'' under the current § 30.4. Under the proposed rule, all sponsors would be required to reach out to a variety of recruitment sources, including organizations that serve individuals with disabilities, to ensure universal recruitment (proposed § 30.3(b)(3)). Including individuals with disabilities among the groups of individuals to be recruited would be a new focus for sponsors. Sponsors would be required to develop a list of recruitment sources that would generate referrals from all demographic groups, including women, minorities, and individuals with disabilities, with contact information for each source. Further, sponsors would be required to notify these sources in advance of any apprenticeship opportunities; while a firm deadline is not proposed, the proposal prefers 30 days notice if possible under the circumstances. This may incur costs to employers due to the additional days of delay in the hiring process resulting from this rule. However, the Department does not have enough information to allow for an estimate of this potential cost.

The kinds of activities we anticipate the sponsor engaging in to satisfy this requirement would include, at a minimum, fostering a relationship with organizations that serve individuals with disabilities, distributing announcements and flyers detailing the job prospects, and may include visiting sites that would likely provide access to individuals with disabilities, and holding seminars. The Department assumed that the cost to sponsors to distribute information to persons with disabilities will be the labor cost of complying with this provision. We also assumed that the labor for this provision will be performed by a human resource manager and an administrative assistant with hourly compensation rates of $68.55 and $22.28, respectively. We assumed that this task will take 30 minutes (0.5 hours) of a human resource manager's time and 30 minutes (0.5 hours) of an administrative assistant's time per targeted location. A sensitivity analysis for a range of time spent conducting outreach to organizations that serve individuals with disabilities was conducted and is presented below. This outreach is expected to include seminars at job sites, webinars, and other forms of outreach. We calculated the cost of this provision per affected sponsor by multiplying the time each staff member devotes to this task by their associated hourly compensation rates. We then multiplied the total labor cost by the number of locations (five) and by the total number of sponsors.[65] The resulting cost for this proposed provision is $5.2 million in the first year, with an average annual cost of $8.4 million over the 10-year analysis period.

Because the universal outreach may involve several different types of activities, the Department included a sensitivity analysis on the total time allocated to universal outreach. Mirroring the calculation above, the Department estimated a low allocation of time (15 minutes, or 0.25 hours) and a high allocation of time (1 hour and 15 minutes, or 1.25 hours) for both the administrative assistant and the human resource manager. The resulting range of costs for the first year is $2.6 million to $13.0 million with an average annual cost ranging from $4.2 to $21 million.[66]

[62] We estimated the 2015 labor cost by multiplying the estimated time to complete the task by the hourly compensation rate of an administrative assistant and by the total number of sponsors in 2015 to obtain a total labor cost of $42,557 (0.08 × $22.28 × 23,014). We then estimated the materials cost by multiplying the per-sponsor materials cost by the total number of sponsors in 2015 to obtain a total materials cost of $3,452 ($0.15 × 23,014). We summed the two costs to obtain a total cost in 2015 of $46,009 ($42,557 + $3,452) for this provision. We repeated this calculation for each year of the analysis period, using the projected number of new sponsors.

[63] We calculated the hourly compensation rate for an apprentice by multiplying the median hourly wage $13 (as published by PayScale for apprentice electrician) by 1.43 to account for private-sector employee benefits (source: OES survey). Thus, the hourly compensation rate for an apprentice is $18.59 ($13 × 1.43).

[64] We calculated the hourly compensation rate for a journeyworker by multiplying the median hourly wage $25.50 (for a journeyworker electrician) by 1.43 to account for private-sector employee benefits (source: OES survey). Thus, the hourly compensation rate for a journeyworker electrician is $36.47 ($25.50 × 1.43).

[65] To estimate the cost of this provision, we calculated the labor cost per affected sponsor by multiplying the time required for the task by the hourly compensation rate for both a human resource manager ($68.55 × .5 = $34.27) and an administrative assistant ($22.28 × .5 = $11.14). We then multiplied the total per-sponsor labor cost by the total number of sponsors in 2015 (23,014) and by the five sites for which each sponsor is to provide outreach. This results in a total cost of $5.2 million (($34.27 + $11.14) × 23,014 × 5) in 2015. We repeated this calculation for each year of the analysis period, using the projected number of sponsors for each year.

[66] To estimate the range of costs for this provision, we calculated the labor cost per affected sponsor by multiplying the time required for the task by the hourly compensation rate for both a

Continued

The Department requests data from the public on how the addition of universal outreach to organizations that serve individuals with disabilities is expected to impact sponsors.

Fourth, the proposed rule would require that all sponsors develop and implement procedures to ensure that its apprentices are not harassed because of their race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability and to ensure that the workplace is free from harassment, intimidation, and retaliation (proposed § 30.3(b)(4)(iv)). As explained in the preamble above, this proposed requirement should not result in any new burdens on sponsors who are already subject to Federal laws that prohibit harassment in the workplace. Because title VII, Executive Order 11246 as amended by Executive Order 13672, the ADEA, GINA, and the ADA prohibit these actions, and most sponsors are already subject to these laws, many sponsors are already undertaking these actions.

Benefits

By hiring more workers from underrepresented groups, firms naturally create mentors and expand networking opportunities for these groups.[67] Mentors are essential not only for recruiting purposes but also as a retention strategy since they provide a support mechanism for new hires.[68] Retention is a direct benefit to sponsors since they will not lose their initial investment in recruiting and training the apprentice. Education and training investments help individuals from underrepresented groups and have positive overall effects, since they improve job performance. Improved job performance and retention due to investments in training and education yields better productivity and efficiencies in labor markets.

d. Revised Methodology for Utilization Analysis and Goal Setting

The proposed rule would streamline the utilization analysis required of sponsors with five or more apprentices and clarify when and how utilization goals are to be established (proposed §§ 30.5 through 30.7). Specifically, the proposed rule would require sponsors to consider just two factors when determining the availability of individuals for apprenticeships rather than the five currently listed in the part 30 regulations. In addition, the proposed rule explains in clear terms the steps required to determine whether any particular groups of individuals are being underutilized and would provide direction as to when and how goals are to be established.

Benefits

The proposed methodology for utilization analysis and goal setting represents a benefit to sponsors because it would reduce the time a sponsor would need to complete it. To estimate the benefits of the proposed methodology as compared to the current methodology, the Department conducted an informal simulation to determine the difference in time to complete the analysis and goal setting by each methodology.[69] According to the simulation, the baseline methodology takes about two hours to complete while the proposed methodology takes one hour to complete. Thus, there is one hour of time savings associated with the proposed methodology for utilization analysis and goal setting.

To monetize the benefits of this time savings, we multiplied this one hour of time savings by the hourly compensation rate of a human resource manager ($68.55) and by the number of active sponsors who employ five or more apprentices (23,014 × 25 percent = 5,754). This calculation results in a benefit to sponsors of $0.39 million in the first year due to the time savings from the proposed methodology and an average annual benefit of $0.58 million over the 10-year analysis period.[70]

e. Requiring Targeted Outreach, Recruitment, and Retention for Underutilized Groups

In addition to the normal outreach, recruitment, and retention activities required of all sponsors under proposed § 30.3(b), this NPRM would require a sponsor of an apprenticeship program, whose utilization analyses revealed underutilization of a particular group or groups of individuals pursuant to proposed § 30.6 and/or who has determined pursuant to proposed § 30.7(f) that there are problem areas with respect to its outreach, recruitment, and retention activities, to engage in targeted outreach, recruitment, and retention for all underutilized groups in proposed § 30.8. We assume that this additional outreach will happen in the same manner as the universal outreach discussed above.

We further assume that this targeted outreach, recruitment, and retention would be newly required for individuals with disabilities of all sponsors who employ five or more apprentices, failed to meet the 7 percent utilization goal, and their current recruitment efforts are not effective and need to be revised, since the proposed rule would now require that such sponsors engage in affirmative action of individuals with disabilities. The Department recognizes, however, that some sponsors may already be meeting the 7% utilization goal for persons with disabilities. Others may be employing them at less than 7%, but nevertheless do not need to engage in targeted outreach and recruitment because their review of their activities did not reveal any barriers to equal opportunity. Therefore, the analysis below may be overestimating those who need to engage in targeted outreach and recruitment. Unfortunately, there are no available data for us to determine how many sponsors are or are not utilizing individuals with disabilities at a rate to be expected. The Department requests data or information from the public on the number of sponsors who employ five or more apprentices as well as the number of sponsors who currently employ individuals with disabilities.[71]

human resource manager ($68.55 × .25 = $17.14 for the low cost and $68.55 × 1.25 = $85.69 for the high cost) and an administrative assistant ($22.28 × .25 = $5.57 for the low cost and $22.28 × 1.25 = $27.85 for the high cost). We then multiplied the total per-sponsor labor cost by the total number of sponsors in 2015 (23,014) and by the five sites for which each sponsor is to provide outreach. This results in a total cost of $2.6 million for the low time assumption (($17.14 + $555.57) × 23,014 × 5) and $13.0 million for the high time assumption (($85.6927+ $27.85) × 23,014 × 5) in 2015. The Department used the growth rate of apprenticeship programs ranging from 5% to 20% by industry to achieve a goal of doubling the number of sponsors in 5 years.

[67] Blau and Winkler (2005), ''Does Affirmative Action Work?'', Countering Stereotypes by Changing the Rules, Regional Review Q1.

[68] Dabke, S; Salem, O; Genaidy, A, et al. (2008). ''Job Satisfaction of Women in Construction Trades,'' *Journal of Construction Engineering and Management,* March 2008.

[69] An employee who had no prior experience gathering demographic data completed this simulation to accurately estimate the time that would be spent on this task by a sponsor who is not familiar with retrieving the required data.

[70] To calculate the benefits of this provision for 2015, we multiplied the hourly compensation rate for a human resource manager ($68.55) by the time saved per sponsor (1 hour), by the total number of sponsors, and by the percent that employ five or more apprentices (25%). This calculation resulted in a total benefit to sponsors of $0.33 million ($68.55 × 1 × 23,014 × 25%) for 2015. We repeated this calculation for the nine remaining years in the analysis period using the projected number of active sponsors for each year. Because the number of apprenticeship sponsors is projected to increase from 23,014 in 2015 to 56,655 in 2014, the annual benefit would also increase over time.

[71] For this analysis, we assumed that the percent of all sponsors employing five or more apprentices (25 percent) remains constant throughout the 10-year analysis period. In reality, this percentage will fluctuate as sponsors take on new apprentices and as apprentices complete their programs. We also expect that, over time, successful outreach will lead to more hiring of persons with disabilities and that

Costs

We assumed that the cost to sponsors to distribute information about apprenticeship opportunities to organizations serving individuals with disabilities will be the labor cost. We also assumed that the labor for this provision will be performed by a human resource manager and an administrative assistant with hourly compensation rates of $68.55 and $22.28, respectively. Lastly, we assumed that this additional outreach will first occur three years after the rule goes into effect.

The Department estimated that this dissemination task will take 30 minutes (0.5 hours) of a human resource manager's time and 30 minutes (0.5 hours) of an administrative assistant's time per targeted location. A sensitivity analysis for a range of time spent conducting targeted outreach to organizations that serve individuals with disabilities was conducted and is presented below. The cost of this provision per affected sponsor is the time each staff member devotes to this task multiplied by their associated hourly compensation rates. This calculation resulted in a labor cost of $45.41 (($68.55 × 0.5) + ($22.28 × 0.5)) per location. We then multiplied this total labor cost by the number of locations (5) and by the number of sponsors with five or more apprentices (2.5 percent of the total number of sponsors whose utilization analyses revealed underutilization of a particular group or groups of individuals in the third year, or 757 (30,291 × 2.5 percent)).

Finally, we assumed that this additional outreach will occur when sponsors who underutilize persons with disabilities are identified by the Department from the results of random audits and that this process will begin in 2018 giving sponsors the opportunity to meet these EEO requirements. This calculation results in a total cost for this provision of approximately $0.17 million in 2018. The average annual cost over the 10-year analysis period is $0.24 million.

The Department requests data from the public on how the targeted outreach to organizations that serve individuals with disabilities is expected to impact sponsors.

The proposed rule would require sponsors to review personnel processes annually (proposed § 30.9), or every two years if it meets the requirements set forth in proposed § 30.4(e)). As required by the 1978 Final Rule (the analysis baseline), sponsors with five or more apprentices in a registered apprenticeship program are required to develop and maintain an affirmative action program. The scope of each sponsor's program depends on the size and type of its program and resources. However, each sponsor is required, under the current rule, to undertake a significant number of appropriate activities to satisfy its affirmative action obligations. The 1978 Final Rule lists examples of the kinds of activities expected, including ''periodic auditing of the sponsor's affirmative action programs and activities'' (29 CFR 30.4(c)(10)). We assume that, at the very least, these program sponsors currently conduct this audit on an annual basis because elsewhere in the 1978 Final Rule, sponsors are required to review their affirmative action programs annually and update them where necessary (29 CFR 30.8). Accordingly, we do not believe that this proposed requirement will result in any additional cost to the sponsor. For sponsors who meet the requirements for biannual review under proposed § 30.4(e), there may be a cost reduction; however, we cannot accurately quantify it due to data limitations on the number of sponsors who would meet the annual requirements for review.

This NPRM proposes that sponsors be required to review their personnel activities at least annually (or every two years, per proposed § 30.4(e)). Requiring this scheduled review of personnel processes would emphasize the philosophy the Department intends to convey throughout the regulation that affirmative action is not a mere paperwork exercise but rather a dynamic part of the sponsor's management approach. Affirmative action requires ongoing monitoring, reporting, and revising to address barriers to EEO and to ensure that discrimination does not occur.

g. Simplified Procedures for Selecting Apprentices

Under the 1978 Final Rule, selection of apprentices must be made using one of four specific selection methods. Under this NPRM (proposed § 30.10), a sponsor would be required to adopt any method for the selection of apprentices provided that the method (1) complies with UGESP; (2) is uniformly and consistently applied to all applicants and apprentices; (3) complies with the qualification standards set forth in title I of the ADA; and (4) is facially neutral in terms of race, color, religion, national origin, sex, sexual orientation, age (40 or older), and disability. This approach greatly simplifies the regulatory structure currently governing selection procedures and affords sponsors with greater flexibility in fashioning a selection procedure; it also would align this provision of part 30 with how other equal opportunity laws regulate an employer's use of selection procedures.

Benefits

This provision aimed at simplifying selection procedures should reduce the sponsor's cost of compliance because we expect that sponsors will be able to more quickly and easily adopt a method for selection consistent with how they are selecting applicants or employees under other EEO laws. The Department requests data or information on the extent the simplification of selection procedures benefits sponsors.

h. Standardizing Compliance Review Procedures for Registration Agencies

The proposed rule would standardize procedures Registration Agencies must follow for conducting compliance reviews (proposed § 30.13). The proposed provision on compliance reviews would carry forward the current provision at § 30.9 addressing compliance reviews and would include several modifications to improve readability. First, the proposed rule would revise the title from ''Compliance reviews'' to ''Equal employment opportunity compliance reviews'' to clarify that the reviews are to assess compliance with the part 30 regulations and not the companion regulations at part 29.

Second, the term ''Registration Agency'' would be used throughout proposed § 30.13 instead of the term ''Department,'' because this section applies to both the Department and to SAAs when conducting an EEO compliance review.

Third, the proposed rule would provide more specificity for the procedures Registration Agencies must follow in conducting compliance reviews. This increased specificity would provide for greater consistency and standardization of procedures across the National Registered Apprenticeship System. For instance, proposed § 30.13(b) would require the Registration Agency to notify a sponsor of the Agency's findings through a written Notice of Compliance Review Findings within 45 days of completing a compliance review. The Notice of Compliance Review Findings must include whether any deficiencies (*i.e.,* failures to comply with the regulatory requirements) were found, how they are to be remedied, and the timeframe within which the deficiencies must be corrected. The Notice of Compliance Review Findings also must notify a

sponsors will meet their recruitment goals and not be required to complete this additional outreach.

sponsor that sanctions may be imposed for failing to correct the aforementioned deficiencies.

These changes would add clarity to the procedures but would not fundamentally change the process and, therefore, would not represent a significant additional burden to sponsors or SAAs. The Department believes the additional specificity will ease some of the burden on States; however the Department requests public comment on how these procedures affect the burden for sponsors and SAAs.

Sponsors are subject to random onsite or offsite compliance reviews by either the SAA or OA where the corresponding agency is expected to notify the sponsor of the review findings. Although the notice of compliance reviews already occurs with SAAs and OA, this NPRM would make the practice standard and common among all entities. Under this NPRM, the notice of review findings would be required to be sent via registered or certified mail, with return receipt requested within 45 days of the completed equal opportunity compliance review.

Costs

The costs associated with this provision would be limited to the use of registered mail, the cost of materials, and the labor cost to send the letter. The actual review process remains unchanged from the 1978 Final Rule. To determine the cost of the notice of compliance reviews, we estimated the labor cost to mail and compile the notice (assumed to be completed by an administrative assistant) and the cost of materials to send the notice. The labor cost is comprised of the time an administrative assistant dedicates to the task (15 minutes, or 0.25 hours) multiplied by the hourly compensation rate ($28.33 for SAAs and $31.50 for OA).[72] The total materials cost is the cost to send a letter via registered mail ($11.25) plus the cost of the envelope ($0.07) plus the cost to photocopy the one-page document ($0.15), or $11.47 ($11.25 + $0.07 + $0.15).

To estimate the total cost of this provision in the first year, we summed labor and material costs and then multiplied by the total number of reviewed sponsors resulting in $18,100 for SAAs and $18,790 for OA.[73] We then repeated this calculation for each year of the analysis period using the projected number of sponsors for each year. The annual average cost to SAAs amounts to $0.02 million and the annual average cost to OA amounts to $0.02 million over the 10-year analysis period.

i. Clarifying Complaint Procedures

This NPRM would require sponsors to establish and implement procedures for handling and resolving complaints about harassment based on race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, and disability (proposed § 30.3(b)(4)(iv)). Because harassment is a form of employment discrimination that violates Federal laws applicable to most sponsors, including title VII, Executive Order 11246, the ADEA, GINA, and the ADA, we expect that most sponsors already have complaint procedures in place. Thus, this proposed requirement should not impose any new burdens on sponsors who must already take the necessary action to prevent and eliminate harassment in the workplace.

Also, in an effort to ensure consistency with how Registration Agencies process complaints and conduct investigations, proposed § 30.14(c) would add uniform procedures that Registration Agencies must follow. These uniform procedures would ensure that Registration Agencies acknowledge and thoroughly investigate complaints in a timely manner, that parties are notified of the Registration Agency's findings, and that the Registration Agency attempts to quickly resolve violations through voluntary compliance. Since the complaint process is not a new process, the Department does not expect that these provisions would add significantly to the burden on Registration Agencies, they simply would standardize the procedures and define a timeline. Therefore, while the Department does not expect significant changes in burden, there may still be one-time costs as Registration Agencies adjust their complaint procedures to reflect newly standardized requirements. These procedures will benefit both sponsors and apprentice complainants since claims will be handled in a clear and consistent fashion. The Department requests more data or information on how these proposed complaint procedures are expected to burden and/or benefit sponsors, apprentices, and Registration Agencies.

j. Adopting Uniform Procedures Under 29 CFR Parts 29 and 30 for Deregistration, Derecognition, and Hearings

The proposed rule would adopt 29 CFR part 29 procedures for deregistration of apprenticeship programs, derecognition of SAAs, and hearings (proposed §§ 30.15 through 30.16). For consistency and simplicity, proposed § 30.15(c) would adopt the deregistration procedures of § 29.8(b)(5) through (8) of this title, including the hearing procedures in § 29.10. This revision would allow SAAs to follow a single set of procedures for all matters arising from management of the National Registered Apprenticeship System. As explained in the preamble above, the Department proposes to incorporate the part 29 procedures for hearings into part 30 so that a sponsor need only follow one set of procedures regardless of whether the issue at hand addresses the labor standards set forth in part 29 or the EEO standards set forth in part 30. These provisions are not expected to impose a burden because SAAs are already following these procedures in part 29.

l. Invitation to Self-Identify as an Individual With a Disability

Proposed § 30.11 requires sponsors, as part of their general duty to engage in affirmative action, to invite applicants for apprenticeship to voluntarily self-identify as an individual with a disability protected by this part at three stages: (1) At the time they apply or are considered for apprenticeship; (2) after they are accepted into the apprenticeship program but before they begin their apprenticeship; and (3) once they are enrolled in the program.

The purpose of this section is to collect important data pertaining to the participation of individuals with disabilities in the sponsor's applicant pools and apprenticeship program. This data will allow the sponsor and OA to better identify and monitor the sponsor's enrollment and selection practices with respect to individuals with disabilities and also enable OA and the sponsor to assess the effectiveness of the sponsor's recruitment efforts over time, and to refine and improve the sponsor's recruitment strategies, where necessary. In addition, data related to apprentices once they are in the program will help sponsors assess whether there may be barriers to equal

[72] We calculated the hourly compensation rate for an administrative assistant by multiplying the hourly wage of $18.64 (GS–7 step 5) by 1.52 for the State agency and 1.69 for the Federal agency to account for public-sector employee benefits. Thus, the hourly compensation rate for an administrative assistant at a State agency is $28.33 ($18.64 × 1.52) and $31.50 ($18.64 × 1.69) at a Federal agency.

[73] To calculate the labor cost, we multiplied the time required by the hourly compensation rate, resulting in a cost of $7.16 (0.25 × $28.64) for State Apprenticeship Agencies and $7.87 (0.25 × $31.50) for OA. We then multiplied each labor cost by the percentage of sponsors subject to compliance reviews (10 percent) and by 50 percent (we assumed that half of the sponsors respond to State Apprenticeship Agencies and half respond to OA).

opportunity in all aspects of apprenticeship and may inform the effectiveness of retention strategies or whether such strategies are necessary.

The Department estimated that each of the 23,014 sponsors in the first year (2015) will need to develop a self-identification invitation, which must be separate from the application, for pre-offer, post-offer, and post-enrollment stages. The Department estimated that a human resource manager ($68.55) will spend 1 hour to develop a self-identification invitation and the burden for this is $1,577,609 in the first year (2015).

The Department estimated that an applicant ($18.59) would take on average 5 minutes (0.08 hour) to complete the invitation. The Department also estimated that there will be an average of 10 applicants per job listing, with an average of 5 listings per sponsor per year. The burden at the stage of pre-offer in the first year (2015) is estimated at $1,738,247 (23,014 sponsors × 5 listings × 10 applicants × 0.08 hour × $18.59). The burden at the stages of post-offer and post-enrollment is estimated at $173,825 (23,014 sponsors × 5 listings × 0.08 hour × $18.59), respectively.

In addition, the Department estimated that an administrative assistant ($22.28) would spend 0.5 hours to record and keep invitations in a data analysis file. The burden for this is estimated at $256,376 (23,014 sponsors × 0.5 hour × $22.28).

Total cost for this provision is approximately $3.96 million in the first year (2015). The average annual cost over the 10-year analysis period is $3.93 million.

j. Other

In addition to the changes discussed above, the proposed rule also would result in three additional costs. First, SAAs would be required to revise their State equal opportunity plan to conform to the new requirements. Second, sponsors would need to learn about the new processes and requirements during the first year of the rule's implementation. Furthermore the NPRM would create an intermediary step between a registered sponsor and a deregistered sponsor (registration suspension). Third, sponsors would likely hire and/or retain more qualified apprentices with disabilities under the proposed rule and this may result in additional costs of providing appropriate job accommodations. The Department seeks comment regarding the amount of additional costs of providing appropriate job accommodations that would not otherwise be captured by sponsors' current accommodation requirements under federal or state disability laws.

Revision of State Equal Opportunity Plan

The process of updating a State equal opportunity plan may potentially involve various different people at different stages of implementation. Updating the plan will include drafting the new plan and completing all administrative procedures that may apply, such as revisions to a State's apprenticeship law or policy that may require a public notice and comment period, training for SAA staff on the revised State EEO Plan, and outreach to program sponsors to inform them of the relevant aspects of the revised State EEO plan, once it has been approved by the Department. The updates to State equal opportunity plans would include changing language and current requirements such that they align with the regulatory changes proposed herein. To calculate the costs, the Department assumed that the process to revise the State equal opportunity plan would take a full year of effort (or 2,080 hours) to complete.[74] This is the Department's best estimate for updating the current State equal opportunity plan; the Department requests data or information from the public on the burden for updating State EEO plans. For simplicity, we assumed that an SAA human resource manager will complete the task at an hourly compensation rate of $59.75.[75] This amounts to an initial cost of $3.11 million and an average annual cost of $0/31 million over the 10-year analysis period.[76]

Intermediate Step Between a Registered Sponsor and a Deregistered Sponsor

Finally, the NPRM proposes the creation of an intermediary step between a registered sponsor and a deregistered sponsor (proposed § 30.15(b)). Currently, deregistration of an apprenticeship program occurs when the sponsors fails to demonstrate compliance with the 1978 Final Rule. The proposed suspension step would allow sponsors an adequate span of time to update their practices and be in compliance without having to be deregistered and then reregistered at a later date. Under this proposed procedure, a Registration Agency would suspend a registration of new apprentices until the sponsor has achieved compliance with part 30 through the completion of a voluntary compliance action plan or until a final order is issued in formal deregistration proceedings initiated by the Registration Agency.

The intermediary step represents a benefit because it would allow sponsors to become compliant without having to be deregistered and then reregister or abandon their program. The benefits of this proposed provision are difficult to quantify because some programs eligible for deregistration may seek deregistration voluntarily. Voluntary deregistration, however, can occur for several reasons and it would be incorrect to assume that all voluntary deregistrations directly correlate with sponsors who would have been deregistered.

The Department expects that fewer programs will be required to deregister or voluntarily deactivate as a result of the proposed suspension procedure, enabling more active total sponsors and the associated apprenticeship opportunities. Instead of losing these potential registered apprenticeship programs, they will persist while upholding equal opportunity hiring practices.[77]

Workplace Accommodations for Apprentices With Disabilities

The proposed rule prohibits discrimination against individuals with disabilities and requires sponsors to take affirmative action to provide equal opportunity in apprenticeship to qualified individuals with disabilities. With respect to the sponsor's duty to ensure non-discrimination based on disability, the sponsor must provide necessary reasonable accommodations to ensure applicants and apprentices with disabilities receive equal opportunity in apprenticeship. Since

[74] Note that this calculation is only the administrative costs of updating the State equal opportunity plan, as opposed to the costs of implementing the new plan, or any new burdens on State Agencies. Since the updated State equal opportunity plan should reflect the proposed Federal regulations, these costs should be accounted for and addressed elsewhere in the analysis under discussions of costs.

[75] We calculated the hourly compensation rate for a human resource manager at a State agency by multiplying the hourly wage of $33.06 (GS–12 step 5) by 1.52 for the State agency. The hourly compensation rate for a human resource manager at a State agency is thus $50.25 ($33.06 × 1.52).

[76] The estimated time to complete the revisions is 12 months (2080 hours). The 2014 calculation used the hourly compensation rate for a state human resource manager ($59.75) multiplied by 2,080 (the assumed number of work hours in a year) and by the total number of State Apprenticeship Agencies (25) to obtain a total cost of $3.11 million (2,080 × $59.75 × 25). This cost only accrues in the first year of the ten-year analysis period.

[77] In addition, this NPRM clarifies the need for recordkeeping (proposed § 30.11). Better recordkeeping will enable sponsors to better understand their current underutilization practices and be able to easily identify recruitment strategies that have worked in the past.

most, if not all, sponsors already are subject to the ADA as amended, and if a Federal contractor to section 503 of the Rehabilitation Act, sponsors already have a duty under existing law to provide reasonable accommodations for qualified individuals with disabilities and thus there is no new burden associated with any duty to provide reasonable accommodation under part 30, as that duty already exists under existing Federal law. The Department requests data or information on the percentage and types of sponsors, if any, who are not currently required to comply with the ADA and/or section 503 and provide reasonable accommodation. For any sponsor who may not already be required under the law to provide such accommodations, we expect the resulting burden to be quite small. A recent study conducted by the Job Accommodation Network (JAN), a service of the Department's Office of Disability Employment Policy (ODEP), shows that the majority of employers in the study (57%) reported no additional accommodation costs and the rest (43%) reported one-time cost of $500 on average.[78] This study shows that the benefits to employers, such as improving productivity and morale, retaining valuable employees, and improving workplace diversity, outweigh the low cost.

4. Summary of Cost-Benefit Analysis

Exhibit 2 presents a summary of the first year costs of the various proposed rule provisions, as described above. As shown in the exhibit, the total first year costs of the rule provisions are $21.26 million. The Department was able to only quantify benefits of the proposed rule resulting from time savings to sponsors from the new methodology for utilization and goal setting. As discussed above, the estimated benefits of this provision are $0.39 million in the first year.

EXHIBIT 2—SUMMARY OF FIRST-YEAR COST

Provision	Entity affected	Monetized cost ($millions)
1. Post equal opportunity pledge	Sponsor	$0.05
2. Disseminate information to organizations serving the underutilized g	Sponsor	
3. Universal Outreach	Sponsor	5.23
4. Notice of compliance review	SSA	0.02
5. Notice of compliance review	OA	0.02
6. Revision of State EEO Plan	SSA	3.11
7. Time required to read and review NPRM	Sponsor	6.31
8. Orientation and periodic information sessions	Sponsor/Apprentice	2.57
9. Invitation to self-identify as an individual with a disability	Sponsor/Apprentice	3.96
Total First-Year Cost		21.96

Next, Exhibit 3 presents a summary of the monetized costs and benefits associated with this NPRM over the 10-year analysis period. The monetized costs and benefits displayed are the yearly summations of the calculations described above. Costs and benefits are presented as undiscounted 10-year totals, and as present values, using 7 and 3 percent discount rates, respectively.

2015

EXHIBIT 3—SUMMARY OF MONETIZED BENEFITS AND COSTS

Year	Monetized benefits ($millions/year)	Monetized costs ($millions/year)
1. 2015	0.39	21.268
2. 2016	0.43	9.98
3. 2017	0.47	10.93
4. 2018	0.52	12.17
5. 2019	0.57	13.40
6. 2020	0.63	14.80
7. 2021	0.70	16.39
8. 2022	0.78	18.21
9. 2023	0.87	20.30
10. 2024	0.97	22.70
Undiscounted total	6.34	160.15
Total with 7% discounting	4.21	109.61
Total with 3% discounting	5.28	134.98

Primary estimates of the 10-year monetized costs of this NPRM are $109.61 million or $134.98 million (with 7 and 3 percent discounting, respectively). The 10-year monetized benefits of this NPRM are estimated to be $4.21 million or $5.28 million (with 7 and 3 percent discounting, respectively).

The proposed rule includes four general categories of revisions: (1) Changes required to make the rule consistent with the Labor Standards for Registration of Apprenticeship Programs set forth in 29 CFR part 29; (2) changes updating the scope of a sponsor's EEO obligations by including age (40 or older), genetic information, sexual orientation, and disability among the list of protected bases upon which a sponsor must not discriminate; (3)

[78] Beth Loy, ''Accommodation and Compliance Series Workplace Accommodations: Low Cost, High Impact,'' Job Accommodation Network (JAN) (2014), *http://askjan.org/media/lowcosthighimpact.html*.

changes to enhance a sponsor's affirmative action obligations and enforcement efforts by Registration Agencies; and (4) changes to improve the overall readability of the rule. Alignment of the EEO regulations at part 30 with its companion regulations at part 29 is necessary for a cohesive, comprehensive regulatory framework for the National Registered Apprenticeship System.

Due to data limitations, the Department did not quantify several of the important benefits to society provided by the proposed policies. This NPRM is expected to result in several overarching benefits to apprenticeship programs as well as some specific benefits resulting from a clearer, more systematic rule.

As discussed above, equal opportunity policies may lead to both efficiency gains and distributional impacts to society. The proposed rule may reduce barriers to entry in apprenticeship programs for women, minorities, and persons with disabilities, fostering a distributional effect, and may alleviate the inefficiencies in the job market these barriers potentially create.

This NPRM focuses on making the current EEO policy consistent and standard across the National Registered Apprenticeship System. In doing so, several tasks already undertaken by sponsors, apprentices and Registration Agencies have been simplified. For instance, the clarified complaint process better informs apprentices, sponsors, and Registration Agencies of their roles and expectations from the process. This NPRM also develops a simpler methodology for the apprentice selection process and offers sponsors the flexibility to choose a mechanism that aligns with their State's specific equal opportunity regulations. Much of the new language developed provides consistency with current equal opportunity laws and part 29 already applicable to these affected entities. Finally, this NPRM streamlines procedures already in place under the 1978 Final Rule.

The Department did quantify some of the benefits and the various costs associated with the NPRM. The major quantifiable benefit was the reduction in labor hours needed for completing the new methodology for utilization analysis and goal setting. The reduction in labor cost resulted in an average annual savings of $0.63 million.

5. Alternatives

In addition to the proposal set forth in this NPRM, the Department has considered four alternatives. These are: (1) To take no action, that is, to leave the 1978 Final Rule intact; (2) to increase the Department's enforcement efforts of the 1978 Final Rule; (3) to apply the same affirmative action requirements set forth in this proposed rule to all sponsors, regardless of size; and (4) to rely solely on individuals participating in the National Registered Apprenticeship System to identify and report to Registration Agencies potential cases of discrimination based on race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, and disability.

The Department conducted economic analyses of all five alternatives to better understand their costs and benefits and the implied tradeoffs (in terms of the costs and benefits that would be realized) relative to the proposed rule. Below is a discussion of each alternative along with an estimation of their costs and benefits. All costs and benefits use the 1978 Final Rule as the baseline for the analysis. Finally, we summarize the total costs and benefits of each proposed alternative.

a. Propose the Policy Changes Contained in This NPRM

The analysis presented above lays out the calculations of the benefits and costs of the proposed regulation. The proposed regulation offers a middle ground to spread the burden on the Department, SAAs, and the sponsors. It increases the responsibilities of the sponsors and provides more detailed methods to uphold a nondiscriminatory program. As calculated above, the 10-year monetized costs of this NPRM range from $105.44 million to $130.14 million (with 7 and 3 percent discounting, respectively). The 10-year monetized benefits of this NPRM range from $4.21 million to $5.28 million (with 7 and 3 percent discounting, respectively).

b. Take No Action

This alternative yields no additional costs to society because it does not deviate from the baseline, that is, the 1978 Final Rule. This alternative, however, also yields no additional benefits in terms of ensuring equal opportunities for women, minorities, individuals with disabilities, and those ages 40 or older.

c. Increase Enforcement of Original Regulation

This alternative maintains the original 1978 Final Rule but increases the monitoring of apprenticeship programs. This alternative increases the burden on the SAAs and OA to enforce the equal opportunity standards. To determine the cost of this alternative, we assumed that the compliance reviews will occur at a 50 percent rate, implying that sponsors would be evaluated by the Registration Agency (OA or SAAs) on a more frequent basis.

To calculate the cost of this alternative, the Department assumed that each compliance review takes 40 hours to complete. This estimate includes time for preparation, conducting the review, writing up the findings and guidance to sponsors, reviewing and approving the final documents to be provided to sponsors, and providing technical assistance, where appropriate. We multiplied the 40 hours needed to complete a review by the increase in the annual number of reviews by 10 percent (2,301 = 23,014 × 10% in 2015)) by the hourly compensation rate of an SAA human resource manager ($59.75) and by the hourly compensation rate of an OA human resource manager ($66.43).[79] We also multiplied this number by 50 percent, assuming that half of the sponsors would report to a SAA and half would report to OA. The cost of increased compliance reviews in the first year is $2.75 million for SAAs (23,014 × 50 percent × $59.75 × 40 × 10 percent) and $3.06 million for OA (23,014 × 50 percent × $55.87 × 40 × 10 percent).[80] The 10-year costs for this alternative range from $62.0 million to $77.7 million (with 7 and 3 percent discounting, respectively).

Exhibit 4 presents a summary of the monetized costs of this alternative option over the 10-year analysis period. Costs are presented as undiscounted 10-year totals, and as present values, using 7 and 3 percent discount rates, respectively.

[79] We calculated the hourly compensation rate for a human resource manager at OA by multiplying the hourly wage of $33.06 (GS–12 step 5) by 1.69 to account for public-sector employee benefits. The hourly compensation rate for a human resource manager at a Federal agency is thus $55.87 ($33.06 × 1.69).

[80] To estimate the full cost of this alternative, we also considered the cost to read and review the new regulation for both sponsors ($2.7 million) and State Apprenticeship Agencies ($2,512 = 2 hours × 25 State Apprenticeship Agencies × $50.25), as calculated above for the proposed regulation.

EXHIBIT 4—COSTS OF INCREASING ENFORCEMENT

[$ millions]

Year	Costs	Sponsors	SAA	OA
2015	$6		$2.75	$3.06
2016	6.4		3.01	3.34
2017	7.0		3.30	3.66
2018	7.6		3.62	4.02
2019	8.4		3.99	4.43
2020	9.3		4.41	4.90
2021	10.3		4.88	5.43
2022	11.5		5.43	6.03
2023	12.8		6.05	6.73
2024	14.3		6.77	7.53
Undiscounted Total	93.3		44.20	49.14
Total with 7%	62.0			
Total with 3%	77.7			

Increasing monitoring and evaluation of current efforts may not improve compliance, nor would it necessarily result in improved access to apprenticeship opportunities for all qualified applicants.

d. Apply the Same Affirmative Action Policy to All Sponsors Regardless of Size

The 1978 Final Rule and the proposed rule require that all sponsors with five or more apprenticeships maintain and update their AAPs. This alternative would apply the same AAP to all sponsors regardless of size. The Department believes that the incremental benefit of this action would be minimal compared to its incremental cost. This policy directly impacts the segment of the population that both qualifies as a small entity and also has few apprentices. We believe that the original 1978 Final Rule restriction of requiring only those sponsors with five or more apprentices to develop, maintain, and update their AAPs is an appropriate way to not disproportionately burden small entities.

To calculate the cost and benefits of this alternative, the Department completed the same calculations conducted for the proposed rule but increased the number of sponsors who have to establish an AAP. This new calculation assumed that all sponsors must determine utilization rates and participate in targeted outreach and recruitment. This alternative increases the costs of the regulation, but we do not believe that it significantly increases the benefits because approximately 90 percent of apprentices in OA programs are currently in the 25 percent of programs that employ 5 or more apprentices.

Although the new utilization methodology saves sponsors time as compared to the provisions of the 1978 Final Rule, expanding the requirements to all sponsors increases the compliance burden on those sponsors who have less than five apprentices. For this alternative, the new utilization methodology is now considered an increased burden on those sponsors who employ less than five apprentices. This new utilization methodology is, however, still considered a benefit to those sponsors who already had to set goals (those with five or more apprentices).

Although this is the only benefit the Department quantifies, expanding the regulations to cover all sponsors should lead to marginal benefits to society. The Department requests data or information from the public on how greatly these benefits would increase, if the regulations were applied to all sponsors, as opposed to only sponsors with five or more apprentices.

To calculate the costs associated with this alternative, we first calculated the cost for those sponsors with fewer than five apprentices to complete the utilization analysis. As discussed above, we assumed this process takes one hour of a human resource manager's time at an hourly compensation rate of $68.55. We then multiplied this amount by 75 percent (the assumed percentage of sponsors who have fewer than five apprentices) for a total of 17,260 (23,014 $\times$ 75 percent) sponsors in the first year. The resulting cost in the first year is $1.18 million ($1 \times \$68.55 \times 17{,}260$). We repeated this calculation for each of the remaining years in the analysis period using the estimated number of sponsors for each year, resulting in an average annual cost of $2.2 million.

We next calculated the costs of expanding the requirements to all apprentices for the targeted outreach. The cost of targeted outreach and recruitment mirrors the cost above except that we no longer scale it by the 25 percent of sponsors who need to set goals. We again assumed that each sponsor contacts three organizations; that a human resource manager would take 30 minutes (0.5 hours) to complete this task at an hourly compensation rate of $68.55; and that an administrative assistant would spend 30 minutes (0.5 hours) at an hourly compensation rate of $22.28. We also multiply this total by the percent of sponsors reviewed each year by either the corresponding SAA or OA. The resulting cost in the third year after implementation of the rule is $0.69 million.

The remaining costs for this alternative are the same as was calculated above for the proposed regulation. The total 10-year costs of this alternative range from $126.55 million to $157.45 million (with 7 percent and 3 percent discounting, respectively).

Sponsors of small apprenticeship programs are often quite small with few employees. Such sponsors would likely be overly burdened by the targeted outreach, recruitment, and retention requirements in proposed § 30.8. For example, they might not have the staff and resource capacity to adequately handle large numbers of applications for one or two apprenticeship positions.

e. Rely on Individuals Participating in the National Registered Apprenticeship System To Identify and Report Potential Cases of Discrimination

Under this alternative, individuals participating in the National Registered Apprenticeship System would be responsible for identifying and reporting to Registration Agencies potential cases of discrimination, in contrast to both the current and proposed part 30 regulatory structures, which require Registration Agencies to monitor and enforce the EEO and affirmative action obligations

via regular compliance reviews. This alternative reduces the burden on sponsors by relying on a complaint-based system. Under this alternative, apprentices' rights for non-discrimination would still be protected, but Registration Agencies would have a more passive role in how they monitor and evaluate program sponsors' compliance with the regulations. OA and SAAs would still conduct compliance reviews (in proposed § 30.11 and current § 30.9) but not as frequently.

Under this alternative, to identify when discrimination may be occurring and whether sponsors are violating the non-discrimination and affirmative action requirements in the part 30 regulations, the Registration Agencies would primarily rely on: (1) The complaints filed under proposed § 30.12 and current § 30.11 and self-evaluations from sponsors, and (2) a process where sponsors conduct a self-evaluation and report back to the Registration Agency.

Registration Agencies would provide sponsors with a format and process to conduct a self-evaluation relative to their compliance with these EEO regulations. Sponsors would then submit their self-evaluation to the Registration Agency for review and analysis. If the Registration Agency is satisfied with the findings from the self-evaluation, the sponsor would be informed accordingly, and no additional actions would be necessary at that time. If the Registration Agency's review of sponsor's self-evaluation identifies deficiencies, then the Registration Agency would conduct an on-site review and provide technical assistance as appropriate.

These complaints and self-evaluations would serve as a ''trigger'' for Registration Agencies to adopt a more active role of visiting program sites to conduct compliance reviews and provide technical assistance, as appropriate.

To estimate the cost of this alternative, the Department assumes that the SAA and OA reduce the number of compliance reviews by 20 percent. To calculate this cost saving we multiplied the total number of active sponsors (23,014 in 2015) by the percentage decrease in reviews. This results in 4,603 fewer reviews in year 2015. We then multiplied the total number of reviews by 50 percent assuming that the SAAs handle half the reviews and OA handles the remaining half. Finally, we multiplied the total reduction in reviews by each agency 2,301 ($0.5 \times 4{,}603$) by the hours needed to complete each review (40 hours) and by the human resource managers' wages ($59.75 and $66.43, for the SAAs and OA, respectively). The resulting cost savings in 2015 is $5.5 million ($2{,}301 \times \$59.75 \times 40$) for SAAs and $6.12 million ($2{,}301 \times \$66.43 \times 40$) for OA. This calculation was repeated for each year using the projected number of sponsors resulting in an average annual savings for the SAAs of $8.84 million and $9.83 million for OA.

To estimate the cost of completing the self-evaluations, the Department assumes that each sponsor completes one evaluation each year and that the sponsor will dedicate 8 hours to complete this review. We multiplied this labor time by the hourly compensation rate of a human resource manager ($66.43) and by the total number of sponsors (23,014). The cost to the sponsors is thus $12.23 million ($23{,}014 \times 1 \times 8 \times \$66.43$) in 2015. This calculation was repeated according to the projected number of sponsors each year, with an average annual cost of $16.0 million.

The self-evaluations will then be reviewed by either the SAAs or OA. The Department calculates this burden by assuming that half of the evaluations are completed by the SAAs and the rest are completed by OA; thus each agency reviews 11,507 (23,014/2) evaluations each year. We multiplied the number of self-evaluations by the time needed to review the evaluation, 5 hours, and finally by the corresponding hourly compensation rates ($59.75 and $66.43 for the SAAs and OA, respectively). The cost in 2015 is $3.44 million for the SAAs and $3.82 million for OA. This calculation was repeated according to the projected number of sponsors each year, with an average annual cost of $5.52 million for SAAs and $6.14 million for OA.

Lastly, the Department estimated the cost of completing and reviewing the individual complaints. The apprentices would be filling out these individual complaints and although the process existed in the 1978 final rule, the Department expects that through general outreach the number of complaints would increase by 100 per year. We assumed that each individual complaint takes 15 minutes to file (0.25 hours). We then multiplied the 0.25 hours by the compensation rate for an apprentice ($19.85)[81] to estimate a labor cost of $4.96 and a total cost of $496 ($4.96 × 100) each year of the analysis period.

The Department again assumed that half of these complaints go to SAAs and half go to OA, or 50 complaints total for each agency. To calculate the cost, we multiplied the time needed to review each complaint (8 hours) by 50 complaints and by the compensation rate for a human resource manager. The resulting cost in 2013 is $23,900 ($50 \times 8 \times \$59.75$) for the SAAs and $26,572 ($50 \times 8 \times \$66.43$) for OA. This calculation was repeated for the nine remaining years in the analysis period.

This alternative also includes costs of reading and reviewing the NPRM totaling $3.16 million for sponsors and $2,988 for the SAAs, as calculated above. The complaint based alternative would range between $184.7 million and $230.7 million (with 7 and 3 percent discounting, respectively).

The Department believes that this approach to regulating discrimination and non-compliance with the part 30 regulations would not adequately prevent discrimination and promote equal opportunity in apprenticeship programs.

f. Summary of Alternatives

Exhibit 5 below summarizes the monetized benefits, costs, and net present values for the alternatives discussed above. We again use discount rates of 3 and 7 percent, respectively, to estimate the benefits, costs, and net present values of the alternatives over the 10-year analysis period.

EXHIBIT 5—SUMMARY OF ALTERNATIVES

[$ million over 2015–2024]

	Benefits	Costs	Net benefit (NPV)
7-percent discount:			
No Action	0.00	0.00	0.00

[81] According to the RAPIDS database's FY2013 Performance Score Card Report, the estimated average starting wage for apprentices that completed their programs was $15.02 and the estimated average exit wage for apprentices that completed their programs was $24.68. The average of these two wages ($15.02 and $24.68) is $19.85.

EXHIBIT 5—SUMMARY OF ALTERNATIVES—Continued

[$ million over 2015–2024]

	Benefits	Costs	Net benefit (NPV)
Policy Change NPRM	4.21	107.70	−103.49
Increased Enforcement	0.00	62.00	−62.00
Same policies regardless of size	4.21	125.63	−121.42
Complaint-based	124.01	211.41	−87.40
3-percent discount:			
No Action	0.00	0.00	0.00
Policy Change NPRM	5.28	132.55	−127.27
Increased Enforcement	0.00	77.71	−77.71
Same policies regardless of size	5.28	156.30	−151.02
Complaint-based	155.41	264.30	−18.89

Note: Net present values may not subtract precisely due to rounding.

Paperwork Reduction Act (PRA)

As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3506(c)(2)(A). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

The PRA typically requires an agency to provide notice and seek public comments on any proposed collection of information contained in a proposed rule. 44 U.S.C. 3506(c)(2)(B); 5 CFR 1320.8. Persons are not required to respond to the information collection requirements as contained in this proposal unless and until they are approved by OMB under the PRA at the final rule stage. The Department has submitted the identified information collections associated with this NPRM to the OMB for review under the PRA. 44 U.S.C. 3507(d); 5 CFR 1320.11. ETA will publish a notice of OMB's action, when OMB makes a final determination on these information collections.

Public Comments: The Department is soliciting comments concerning proposed changes to two information collection requests (ICRs) that are associated with proposed changes to part 30. OMB previously approved for these two ICRs: (1) OMB Control Number 1205–0223 for information collection required under part 29, Labor Standards for Registration of Apprenticeship Programs, and (2) OMB Control Number 1205–0224 for information collection required under part 30, Equal Employment Opportunity in Apprenticeship Training. Interested parties may obtain a copy of the ICRs by visiting the *http://www.reginfo.gov/public/do/PRAMain* Web site, or by contacting the Office of Apprenticeship, 200 Constitution Avenue NW., Room N–5311, Washington, DC 20210. Telephone: 202–693–2796; Fax: 202–693–3799. These are not toll-free numbers.

The Department specifically seeks comments regarding the burdens imposed by information collection requests associated with this proposed rule. In particular, the Department seeks comments that evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; enhance the quality, utility and clarity of the information to be collected; and minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Comments about the information collections in this NPRM may be submitted to ETA by using the Federal eRulemaking portal at *http://www.regulations.gov* (follow instructions for submission of comments). In addition to filing comments with ETA, interested parties may address comments about the paperwork implications of the proposed regulations to OMB. Comments to OMB should be directed to: Office of Information and Regulatory Affairs, Attention OMB Desk Officer for ETA, Office of Management and Budget, Room 10235, Washington, DC 20503. Telephone: 202–395–7316; Fax: 202–395–6974. These are not toll-free numbers.

OMB requests that comments be received within 30 days of publication of the proposed revisions to the part 30 regulations. Please note that comments submitted to both OMB and DOL are a matter of public record.

Purpose, Use, and Burden Estimate. As previously explained, the part 30 regulations already require apprenticeship program sponsors to provide for equal opportunity for participation in registered apprenticeship programs, and protect apprentices and applicants for apprenticeship from discrimination based on race, color, religion, national origin, and sex. In addition, the regulations require that sponsors of registered apprenticeship programs take affirmative action to provide equal opportunity in such programs.

Under the PRA, information collections include Federal reporting, recordkeeping, and third-party discloser requirements. The existing regulations impose a number of approved information collection requirements that would be unchanged by this NRPM, except as discussed in this preamble. These include information collections related to registration requirements for apprenticeship programs and apprentices, including proper training safeguards; apprenticeship agreements and standards; and recognition requirements for SAAs. The Department obtains OMB approval for this information collection under Control Number 1205–0223 (current expiration date of June 30, 2018).

The NPRM would also continue, except as discussed elsewhere in this preamble, requirements for a sponsor to document that the apprenticeship program conforms to equal opportunity

standards required by these regulations, to maintain records necessary to determine compliance with this part (although the length of time required for recordkeeping maintenance has been shortened from five to three years), to provide all applicants and all apprentices written notice of complaint procedures; and to prepare written AAPs, if required. The NPRM would also continue, except as discussed elsewhere in the preamble, the requirements for SAAs to prepare State EEO plans conforming to these regulations, to maintain adequate records pertinent to compliance with these regulations, and to notify the Department of exemptions from these regulations granted to program sponsors. The Department clears this latter list of information collections with OMB under Control Number 1205–0224 (current expiration date of May 31, 2016).

Recordkeeping requirements described in this NPRM modify previously approved requirements for registered apprenticeship program sponsors and apprentices to submit Apprenticeship Agreement Forms to OA or to the appropriate SAA. These Apprenticeship Agreement Forms include record-keeping information necessary for Registration Agencies to determine if apprenticeship program sponsors are complying with the affirmative steps to ensure non-discrimination required under this NPRM. OMB approved these requirements for the ICR for Apprenticeship Agreement Form (ETA 671) for use under 29 U.S.C. 50 and 29 CFR 29.1 (OMB control number 1205–0223). Responses to this Apprenticeship Agreement Form are required to obtain or retain benefits as registered apprentices. Specifically, this NPRM would add age (40 or older), genetic information, sexual orientation, and disability to the list of bases upon which registered apprenticeship program sponsors must not discriminate.

Therefore, the Department would revise ETA 671, the Apprenticeship Agreement Form, to provide for collection of information, on a voluntary basis, of an apprentice's disability status. Such information would be collected on a separate tear-off sheet that could be maintained separately from the Apprenticeship Agreement Form and treated as confidential. The Department estimates that this modification to ETA 671 will not add any additional response time or cost burden.

The Department has also determined that the proposed rule will not change the paperwork burdens for the first of the three information collections included in the ICR for part 30: ''ETA 9039, Compliant Form—Equal Employment Opportunity in Apprenticeship Programs.'' As discussed above, the NPRM would add age (40 or older), genetic information, sexual orientation, and disability to the list of bases upon which registered apprenticeship program sponsors must not discriminate. The Complaint Form—Equal Employment Opportunity in Apprenticeship Programs (ETA 9039), does not currently include disability status, genetic information, sexual orientation, and age (40 or older) as bases for discrimination.

Therefore, the Department would revise ETA 9039 to enable complainants to file complaints about discrimination on the basis of age (40 or older), genetic information, sexual orientation, and disability. These additions would not add any new or additional time or cost burden to individuals who voluntarily choose to complete and file a complaint form regarding EEO in registered apprenticeship. Based on agency experience administering the National Registered Apprenticeship System, the Department assumes an annual rate of 50 responses requiring 30 minutes (0.5 hours) per response for a total annual burden of 25 hours for this information collection. Exhibit 6 below summarizes the burden hours for Complaint Forms—Equal Employment Opportunity in Apprenticeship Programs.

EXHIBIT 6—INFORMATION COLLECTION FOR ETA 9039 COMPLAINT FORM—EQUAL OPPORTUNITY IN APPRENTICESHIP AND TRAINING

	Currently approved (Current § 30.11)	Proposed rule (Proposed § 30.13)
Total Respondents	50	50.
Frequency	One-time	One-time.
Total Responses	50	50.
Average Time Per Response	0.5 hour	0.5 hour.
Total Burden Hours	25	25.

The NPRM would make some changes to the second information collection in the ICR for part 30 that pertains to SAAs. Responses to this information collection are required for the SAA to retain recognition status as a Registration Agency. The NPRM would carry forward the current part 30's recordkeeping requirements for SAAs and would update these requirements to reflect the use of electronic recordkeeping, and the broadened scope of the regulation to provide for equal opportunity, nondiscrimination, and affirmative action for applicants or apprentices with disabilities. The proposed revisions would not change the hour and cost burden for SAAs' recordkeeping requirements. Based on historical data for the National Registered Apprenticeship System, the Department estimates that the 25 SAAs will register approximately 11,700 new apprentices annually requiring about 5 minutes (0.083 hours) per response. Therefore, the Department estimates the annual paperwork burden at 975 hours (0.083 hours × 11,700 responses = 975 hours). As discussed above, the estimated number of responses would be lower than the estimates of 12,800 new apprentices currently approved for this information collection under OMB Control Number 1205–0224.

The proposed requirement for submission of a revised State EEO plan (proposed § 30.17) would create a one-time paperwork burden that is not included in the currently approved information collections under OMB Control Number 1205–0224. As discussed in the Executive Order 12866 section of the preamble, the Department estimates that process of updating the State's EEO plan for conformity with the requirements of the proposed rule will take a full year of effort (2,080 hours) to complete. The Department estimates a one-time burden of 52,000 hours for this information collection (2,080 hours × 25 responses = 52,000 hours).

Exhibit 7 below summarizes the burden hours for SAAs currently approved under OMB Control Number

1205–0224, and displays the burden hours associated with the NPRM and with the estimates of reduced numbers of responses, as discussed above. SAAs' responses to this information collection are required for the Agency to retain the Department's recognition of the SAA as the Registration Agency for Federal purposes.

EXHIBIT 7—INFORMATION COLLECTION FOR SAAS

Regulatory requirements	Currently approved	Proposed rule
SAA records of apprentices	Current § 30.8	Proposed § 30.17.
Total Respondents	25	25.
Frequency	On Occasion	On Occasion.
Total Responses	12,800	11,700.
Average Time Per Response	0.083 hours (5 minutes)	0.083 hours (5 minutes).
Burden	1,067 hours	975 hours.
State EEO Plan	Current § 30.15	Proposed § 30.17.
Total Respondents		25.
Frequency	One-time	One-time.
Total Responses		25.
Average Time Per Response	0*	2,080 hours.
Burden	Completed in 1978	52,000.
Total Burden Hours	1,067	52,975.

* Last completed in 1978.

The NPRM would change the burden hours associated with the third information collection for part 30, ''Obligations of apprenticeship program sponsors.'' The burden hours for compliance with proposed revisions to equal opportunity standards (proposed § 30.3, Equal opportunity standards applicable to all sponsors) would increase from the currently approved burden of one half-hour to 1.08 hours. This increase is necessary to account for universal outreach to a variety of recruitment sources, including organizations that serve individuals with disabilities, and the 0.08 burden hour required to post the equal opportunity pledge.

The Department estimates that the NPRM would modify the distribution of burden hours for compliance with affirmative action provisions, which ultimately would reduce burden hour estimates for obligations of apprenticeship program sponsors. Under the currently approved paperwork burdens (OMB Control Number 1205–0224), the Department attributes a total of 3,380 burden hours for program sponsors obligations for affirmative action provisions in current § 30.4, affirmative action (1 hour for each new sponsor with five or more apprentices = 180 hours); current § 30.5, selection procedures (0.5 hours for 5,900 active apprenticeship program sponsors with five or more apprentices = 2,950 hours), and § current 30.6, existing list of eligibles and public notice (5 hours for 50 sponsors = 250 hours).

As discussed elsewhere in the preamble, the NPRM would delete the current § 30.6, existing list of eligibles and public notice, and would simplify the regulatory structure governing procedures for selecting apprentices (current § 30.5 and proposed § 30.10). Burden hours for affirmative action obligations in current § 30.5 and 30.6 would be eliminated.

For the proposed rule, the Department estimates five total burden hours for apprenticeship program sponsors' affirmative action obligations in proposed §§ 30.4, 30.5, 30.6, 30.8, and 30.9. These requirements would apply to program sponsors subject to proposed § 30.4(b), the adoption of affirmative action programs. As discussed elsewhere in the preamble, proposed § 30.4(d) carries forward existing exemptions from the requirement to conduct affirmative action programs. Burden hour estimates for these affirmative action obligations are: (1) One hour to develop, maintain, and update a written plan submitted to and approved by the Registration Agency within one year from the time of registration; (2) 0.5 hours for utilization analysis for race, sex, and ethnicity in proposed § 30.5; (3) 0.5 hours for establishment of utilization goals for race, sex, and ethnicity in proposed § 30.6; (4) one hour for outreach, recruitment and retention for targeted groups in proposed § 30.8; and (5) one hour for targeted outreach, recruitment, and retention for individuals with disabilities in proposed § 30.8; and (6) one hour for the review of personnel processes (proposed § 30.9).

Collection of Voluntary Self-Identification of Disability Information: The system for voluntary self-identification for individuals with disabilities is based on the one used by the Office of Federal Contractor Compliance Programs (OFCCP) (see OMB Control Number 1250–0005). Burden hour estimates for apprenticeship voluntary self-identification for individuals with disabilities follow the reasoning that OFCCP developed for the Section 503 rule. Similar estimates are described in the burden analysis and illustrated in Exhibit 8.

The Department proposes to require sponsors to invite applicants to voluntarily self-identify as part of the apprenticeship application process if they are an individual with a disability at three stages: (1) Pre-offer: At the time they apply or are considered for apprenticeship; (2) Post-offer: After they are accepted into the apprenticeship program but before they begin; and, (3) After-Enrollment: Once they are enrolled in the program.

The Department estimates that an applicant would take on average 5 minutes to read and complete a program sponsor's invitation to self-identify a disability. The Department estimates that there will be, on average, 10 applicants per Registered Apprenticeship job listing, and an average of five job openings per year per sponsor. The pre-offer burden is estimated to be 95,508 hours (23,014 sponsors × 10 applicants × 5 job openings per year × 5 minutes). The post-offer burden is estimated to be 9,551 hours based on an average of 5 applicants for the 5 job openings per sponsor per year (23,014 sponsors × 5 applicants per year × 5 minutes). Likewise, the after-enrollment burden is estimated to be 9,551 hours based on an average of 5 apprentices employed in an average of 5 job openings per sponsor per year 23,014 sponsors × 5 new apprentices per year × 5 minutes). The

Department also estimates that an administrative assistant will spend 30 minutes per year to record and file the voluntary reporting of disability information related to this rule. This burden is estimated to be 11,507 hours (23,014 × 30 minutes).

Exhibit 8 below summarizes the burden hours for obligations of apprenticeship program sponsors currently approved under OMB Control Number 1205–0224, and displays the burden hours associated with the NPRM. Responses for information collections regarding program sponsors' obligation are required to obtain or retain benefits as registered apprenticeship program sponsors.

EXHIBIT 8—INFORMATION COLLECTION FOR OBLIGATIONS OF APPRENTICESHIP PROGRAM SPONSORS

Regulatory requirements	Currently approved	Proposed rule
Equal opportunity standards:	Current § 30.3	Proposed § 30.3.
Total Respondents	New sponsors with five or fewer apprentices.	860.
Frequency	One-time	One-time.
Total Responses	1,290	860*.
Average Time Per Response	0.5 hour	1.08 hours.
Burden	645 hours	929 hours.
Affirmative action	Current § 30.4	Proposed § 30.4*.
Total Respondents	180	140.
Frequency	One-time	One-time.
Total Responses	180	140*.
Average Time Per Response	1 hour	5 hours.
Burden	180 hours	700 hours.
Selection of apprentices	Current § 30.3	Proposed § 30.10.
Total Respondents	5,900	0.
Frequency	One-time	0.
Total Responses	5,900	0.
Average Time Per Response	0.5 hour	0.
Burden	2,950 hours	0.
Existing list of eligibles and public notice	Current § 30.6	0.
Total Respondents	50	0.
Frequency	One-time	0.
Total Responses	50	0.
Average Time Per Response	5 hours	0.
Burden	250 hours	0.
Recordkeeping of active apprentices	Current § 30.8	Proposed § 30.11.
Total Respondents	26,700	23,014.
Frequency	One-time	One-time.
Total Responses	26,700	23,014.
Average Time Per Response	0.0167 hour	0.0167 hour.
Burden	445 hours	384 hours.
Voluntary Self-Identification of Disability Information		
Pre-Offer		
Total Respondents	NA	23,014.
Total Responses	NA	10 applicants/job opening.
Frequency	NA	5 job openings/year.
Average Time Per Response	NA	5 minutes.
Burden	NA	95,508 hours.
Post-Offer		
Total Respondents	NA	23,014.
Total Responses	NA	5 applicants/year.
Frequency	NA	Annually.
Average Time Per Response	NA	5 minutes.
Burden	NA	9,551 hours.
After-Enrollment		
Total Respondents	NA	23,014.
Total Responses	NA	5 new apprentices/year.
Frequency	NA	Annually.
Average Time Per Response	NA	5 minutes.
Burden	NA	9,551 hours.
Sponsor Recordkeeping		
Total Respondents	NA	23,014.
Total Responses	NA	23,014.
Frequency	NA	Annually.
Average Time Per Response	NA	30 minutes.
Burden	NA	11,507 hours.
Total Burden Hours	4,470	128,130.

*If sponsors are *not* exempt from § 30.4, then total six burden hours are associated with meeting the requirements of proposed §§ 30.5, 30.6, 30.8, and 30.9.

Exhibit 9 illustrates the total burden hour estimates for the three information collections in the ICR for part 30, as currently approved under OMB Control Number 1205–0224, and as proposed under the NPRM.

EXHIBIT 9—BURDEN SUMMARY OF THREE INFORMATION COLLECTIONS FOR PART 30

[OMB Control Number 1205–0224]

Information collection	Currently approved	Proposed rule
ETA 9039 Complaint Form—Equal Opportunity in Apprenticeship and Training (Exhibit 6)		
Total Respondents	50	50.
Total Responses	50	50.
Burden	25	25 hours.
Information Collection for SAAs (Exhibit 7)		
Total Respondents	25 SAAs	25 SAAs.
Total Responses	12,800	11,725.
Aggregated Burden Hours	1,067	52,975*.
Information Collection For Obligations of Apprenticeship Program Sponsors (Exhibit 8)		
Total Respondents	34,120	116,070.
Total Responses	34,120	47,088.
Aggregated Burden	4,470	128,130.
Totals		
Total Respondents	26,778	116,145.
Total Responses	46,970	58,863.
Aggregated Burden Hours	5,562	181,130.

* SAAs' aggregated burden includes a one-time burden for the process of updating the State EEO plans necessary for conformity with the proposed rule.

Executive Order 13132: Federalism

The Department has reviewed this NPRM in accordance with Executive Order 13132 and found it may have Federalism implications, because it may have substantial direct effects on States and on the relationship between the Federal government and the States. Although matters of Federalism in the National Registered Apprenticeship System are primarily established through part 29, Labor Standards for Registration of Apprenticeship Programs, which establishes the requirements for the recognition of SAAs as Registration Agencies, the proposed revisions to part 30 also have direct effect on a State's method of administering registered apprenticeship for Federal purposes. In particular, this NPRM requires an SAA that seeks to obtain or maintain recognition as the Registration Agency for Federal purposes, to submit a State EEO plan that demonstrates conformity of State apprenticeship law with revised part 30, and requires all program sponsors registered with the State for Federal purposes to comply with the State EEO plan. This NPRM also requires OA's Administrator to provide written concurrence on any subsequent modifications to the State EEO plan, as provided in § 29.13(b)(9) of this title. The Department has determined that these requirements are essential to ensure that SAAs conform to the new requirements of part 30, as a precondition for recognition.

In the development of this NPRM, the Department included several mechanisms for consultation with State officials. In 2010, OA conducted two listening sessions with members of the National Association of State and Territorial Apprenticeship Directors (NASTAD), the organization representing apprenticeship officials from the District of Columbia, 26 States, and three Territories, to request the members' recommendations for updating part 30. Additionally, as discussed earlier in the preamble, OA gave consideration to recommendations from the ACA, whose membership includes representatives from NASTAD and the National Association of State Government Labor Officials (NAGLO). Finally, OA invited State officials to participate in a series of ''town hall'' meetings and a webinar conducted in spring 2010 to elicit the agency's stakeholders' recommendations for updating part 30.

The recommendations that State apprenticeship officials provided through these consultations varied considerably as to their specificity and topics. However, the input received in consultations with State apprenticeship officials was similar to that generated in the sessions with other apprenticeship stakeholders. The shared themes included support for a progressive approach to enforcement; increased outreach efforts; focus on equal training for and retention of all apprentices; clarification of complaint procedures; and simplification of requirements for selection procedures. The Department considered all of these issues, and incorporated them into the proposed rule.

Nevertheless, consistent with Executive Order 13132, the Department specifically solicits comments from State and local government officials on this proposed rule.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This NPRM does not impose any Federal mandates on any State, local, or tribal governments, or the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

Assessment of Federal Regulations and Policies on Families

The Department certifies that this NPRM has been assessed according to section 654 of Public Law 105–277, 112 Stat. 2681, for its effect on family well-being. The Department concludes that this NPRM will not adversely affect the

well-being of the Nation's families. Rather, it should have a positive effect by safeguarding the welfare of registered apprentices.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980, as amended (RFA), requires agencies to review regulations for their impact on small businesses and consider less burdensome alternatives. When proposing regulations that will have a significant effect on a substantial number of small entities, the RFA requires agencies to prepare regulatory flexibility analyses, which describe the impact of the proposed rule on small entities, and make them available for public comment. 5 U.S.C. 603. If the rule is not expected to have a significant economic impact on a substantial number of small entities, the RFA allows an agency to certify this in lieu of preparing the analyses. 5 U.S.C. 605. For the reasons explained in this section, the Department believes this NPRM is not likely to have a significant economic impact on a substantial number of small entities and, therefore, a regulatory flexibility analysis is not required by the RFA.

However, in the interest of transparency and to provide a full opportunity for public comment, we have prepared the following Initial Regulatory Flexibility Analysis to assess the impact of this proposed regulation on small entities, as defined by the applicable Small Business Administration (SBA) size standards. We specifically request comments on the following burden estimates, including the number of small entities affected by the requirements, and on alternatives that could reduce the burden on small entities. The Chief Counsel for Advocacy of the SBA was notified with a draft of this proposed rule upon submission of the proposed rule to OMB under Executive Order 12866, as amended, ''Regulatory Planning and Review.'' 58 FR 51735, 67 FR 9385, 72 FR 2763; 5 U.S.C. 603(a).

1. Classes of Small Entities

A small entity is one that is independently owned and operated and that is not dominant in its field of operation. 5 U.S.C. 601(3); 15 U.S.C. 632. The definition of small entity varies from industry to industry to properly reflect industry size differences. 13 CFR 121.201. An agency must either use the SBA definition for a small entity or establish an alternative definition for the industry. Using SBA size standards, the Department has conducted a small entity impact analysis on small entities in the five industry categories with the most registered apprenticeship programs and for which data were available: Construction, Manufacturing, Service, Transportation and Communication, and Trade.[82] These top five industry categories account for 86 percent of the total number of apprenticeship sponsors who had active apprenticeships during FY2009.[83]

One industry, Public Administration, made the initial top-five list but is not included in this analysis because no data on the revenue of small local jurisdictions were available. Local jurisdictions are classified as small when their population is less than 50,000. 5 U.S.C. 601(5). The Department requests information from the public regarding possible sources of data or information on the number and revenues of small local jurisdictions sponsoring apprenticeship programs.

Registered apprenticeship program sponsors may be employers, employer associations, industry associations, or labor management organizations and, thus, may represent businesses, multiple businesses, and not-for-profit organizations. The requirements of this NPRM, however, fall on the sponsor, and therefore we used sponsor data to create the industry breakdowns. The Department requests information from the public regarding possible sources of data or information on the number and revenues of not-for-profit organizations sponsoring apprenticeship programs.

The Department has adopted the SBA small business size standard for each of the five industry categories. Since the industry categories include multiple NAICS sectors, some industry categories will reflect multiple SBA definitions. We accounted for industries included in each industry category.

The ''Construction'' industry category follows NAICS exactly (NAICS 23) and, thus, we used the SBA definition of revenue less than or equal to $35.5 million.

The ''Manufacturing'' industry category includes the standard sector for Manufacturing (NAICS 31–33), but also covers Logging (NAICS 113310); Sand, Gravel, Clay, and Ceramic and Refractory Minerals Mining and Quarrying (NAICS 21232); and Newspaper, Periodical, Book, and Directory Publishers (NAICS 5111). The corresponding SBA small size standards are as follows: Manufacturing—500 employees or less; Newspaper, Periodical, Book, and Directory Publishers—500 employees or less; Logging and Sand, Gravel, Clay, and Ceramic—revenue less than or equal to $7 million; and Refractory Minerals Mining and Quarrying—revenue less than or equal to $7 million.[84]

The ''Service'' industry category covers the largest number of NAICS sectors, subsectors, and industries.[85] The majority of these industries use the SBA small business size standard of revenue of less than or equal to $7 million, with the exception of Radio, Television, and Other Electronic Stores, which uses $9 million (the average across the industry codes); Motion Picture and Video Production, which uses $29.5 million; and Dental Laboratories, which uses 500 employees or less.

The ''Transportation and Communication'' industry category includes transportation and warehousing (NAICS 48–49), Marinas (NAICS 713930), Other Nonhazardous Waste Treatment and Disposal (NAICS 562219), Telecommunication (NAICS 517), Radio and TV Broadcasting (NAICS 5151), and Utilities (NAICS 221). The SBA size standard for these industries is revenue less than or equal to $7 million for Transportation and Warehousing, Marinas and Telecommunication; $12.5 million for Other Nonhazardous Waste Treatment

[82] According to RAPIDS, the percent of programs (of all sizes) in the selected sectors were as follows: Construction, 40.2 percent; Manufacturing, 26.7 percent; Service, 8.6 percent; Transportation and Communication, 7.3 percent; and Trade, 2.7 percent.

[83] RAPIDS includes a portion of all registered apprenticeship programs and apprentices nationwide because SAAs that are recognized by the Department of Labor to serve as the Registration Agency may choose, but are not required, to participate in RAPIDS. Therefore, RAPIDS includes individual level apprentice and apprenticeship program data for the 25 states in which OA is the Registration agency and 7 SAAs that participate in RAPIDS. Therefore, RAPIDS includes data from 32 of the 50 states and the Department estimates that they represent 55 to 60 percent of all sponsors and 50 to 55 percent of all apprentices. We assume that our data set is a good predictor of the population of apprenticeship programs nationwide.

[84] When an industry breakdown uses multiple sector codes, we used the more specific NAICS code. Typically, the definition of the industry category centers on a particular sector (for example, Manufacturing) but it may also include some satellite industries. For example, Logging is the only industry in Agriculture, Forestry, Fishing, and Hunting (NAICS 11). Thus, including the entire sector would be a poor representation of the ''Manufacturing'' industry category.

[85] The included industry sectors are Arts, Entertainment and Recreation (NAICS 71); Accommodation (NAICS 721); Other Services (NAICS 81); Administrative and Support and Waste Management and Remediation Services (NAICS 56); Professional, Scientific, and Technical Services (NAICS 541); Rental and Leasing Services (NAICS 532); Motion Picture and Video Production (NAICS 512110); Dental Laboratories (NAICS 339116); Radio, Television and Other Electronic Stores (NAICS 44312); Educational Services (NAICS 611); and Health Care and Social Assistance (NAICS 62).

and Disposal; and $10.5 million for Radio and TV Broadcasting.[86]

The ''Trade'' industry category includes Merchant Wholesalers, Nondurable Goods (NAICS 424) and Durable Goods (NAICS 423); Retail Trade (NAICS 44–45); Retail Bakeries (NAICS 311811); and Food Services and Drinking Places (NAICS 722). The associated SBA size standards are: Merchant Wholesalers, Nondurable Goods and Durable Goods—less than or equal to 100 employees, Retail Trade—revenue less than or equal to $7 million, Retail Bakeries—less than or equal to 500 employees and Food Services and Drinking Places—revenue less than or equal to $7 million.

SBA small business size standards are based on a comprehensive survey of industries, and are specific to each industry. Because each industry category covers multiple sectors, each category includes several criteria that can be used to identify small entities.[87] To determine the average number of employees by small entity, the revenue per employee for a small entity, and the percent of entities that qualify as a small entity, we broke down the 2007 Economic Census by these various sectors, subsectors, and industries. We made a calculation separately for each industry and then aggregated these values to obtain estimates for the top five industry categories.

2. Impact on Small Entities

The Department has estimated the incremental costs for small entities from the baseline of the 1978 Final Rule.[88] This analysis reflects the incremental cost of this NPRM, as it adds to the requirements of the 1978 Final Rule. Using available data, we have estimated the costs of the following provisions: Posting of the equal opportunity pledge, disseminating information about apprenticeship opportunities through universal outreach and recruitment, selected sponsors disseminating information about apprenticeship opportunities through targeted outreach, and the time required to read and review the new regulatory requirements.

To examine the impact of this proposed rule on small entities, we evaluated the impact of the incremental costs on a hypothetical small entity of average size. The total number of workers for the average small entity in the different sectors is as follows: Construction, 6.2; Manufacturing, 20.3, Service, 6.6; Transportation and Communication, 6.7; and Trade, 7.5.[89]

Using 2007 Economic Census data, we derived the annual revenues for small entities in each of the top five industry categories by multiplying the average number of workers by the average revenue per worker for each of the sectors. We estimated that small entities in the five sectors considered in this analysis have the following average annual revenues: Construction, $1.28 million; Manufacturing, $4.31 million; Service, $0.72 million; Transportation and Communication, $1.05 million; and Trade, $1.72 million.

A significant economic burden results when the total incremental annual cost as a percentage of total average annual revenue is equal to or exceeds 1 percent.[90] Because the estimated annual burden of the rule is less than 1 percent of the average annual revenue of each industry category, the rule is not expected to cause a significant economic impact to small entities.[91] These entities include individual employers, groups of employers, labor management organizations, or industry associations that sponsor apprenticeships.

A provision-by-provision analysis of the estimated small entity impacts of this NPRM is provided below.

3. Impacts of NPRM Provisions

The following sections present the impacts that this NPRM is estimated to have on small entities that sponsor apprentices. These include: Posting of the equal opportunity pledge, disseminating information about apprenticeship opportunities through universal outreach and recruitment to individuals with disabilities, disseminating information about apprenticeship opportunities through targeted outreach and recruitment, , and reading and reviewing the new regulatory requirements.

The Department estimated the per-entity cost for each one of these changes from the baseline, that is, the 1978 Final Rule. Because all the rule provisions will have a similar impact on entities across economic sectors, we calculated impacts to a representative single entity.[92] As explained in detail below, the total impact amounts to approximately $436 per affected entity in the first year (and a somewhat smaller impact in subsequent years).[93] The analysis covers a 10-year period (2015 through 2024) to ensure it captures costs that accrue over time.

a. Posting of the Equal Opportunity Pledge

This NPRM proposes to require sponsors to post their equal opportunity pledge at each individual sponsor location, including on bulletin boards and through electronic media (proposed § 30.3(b)(2)). The 1978 Final Rule did not contain a requirement for posting the pledge. This proposed provision represents a cost to sponsors, and reflects the time needed to post the document as well as the cost of the materials.

To estimate the labor cost of this provision, we assumed that it would take a sponsor 5 minutes (0.0833 hours), to post the pledge, and that this task would be performed by an administrative assistant at an average hourly compensation rate of $22. 28.[94] We multiplied the time estimate for this provision by the average hourly compensation rate to obtain a total labor cost per sponsor of $1.85 ($22.28 × 0.083).

To estimate the materials cost, we assumed that the pledge is one page, and that the cost per page for photocopying is $0.15, resulting in a materials cost of $0.15 ($0.15 × 1) per sponsor. Summing the labor and materials costs results in an annual per-

[86] Utilities are categorized as small when their total electric output does not exceed 4 million megawatt hours. Because we did not have readily available data on megawatt output, we set aside the Utilities subsector.

[87] The SBA classifies small entities at the industry level but, because our analysis considers affected sectors, we incorporate the most common industry standard for each sector or subsector.

[88] 43 FR 20760 (May 12, 1978) (requiring the inclusion of female apprentices in AAPs).

[89] Source: 2007 County Business Patterns and 2007 Economic Census. These figures originate from the average number of employees and average revenue by employee size for a business that qualifies as a small business based on the sector-specific size standard.

[90] *See* Small Business Association, *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act,* 17–19 (June 2010), *available at http://www.sba.gov/content/guide-government-agencies-how-comply-with-regulatory-flexibility-act-0* (last accessed Apr. 7, 2011). The Department has used the 1 percent threshold in previous regulations.

[91] The ratio of annual costs to average annual revenue for small entities for the year 2010 is as follows: Construction, 0.12 percent; Manufacturing, 0.03 percent; Service, 0.21 percent; Transportation/Communication, 0.14 percent; and Trade, 0.09 percent.

[92] A large entity could have a single apprentice or a small entity could have multiple apprentices.

[93] Because the number of apprentices does not directly correlate with the size of the sponsor, we are unable to account for this difference. To be conservative in its estimate of impacts, the Department assumed that the time to complete the review process is independent of the size of the entity and applied the same cost of this provision to entities regardless of their size.

[94] The hourly compensation rate for an administrative assistant was calculated by multiplying the average hourly wage of $15.58 (as published by the Department's OES survey, O*NET Online) by 1.43 to account for private-sector employee benefits (source: BLS). Thus, the hourly compensation rate for an administrative assistant is $22.28 ($15.58 × 1.43).

entity cost of $2.00 ($1.85 + $0.15) due to this provision.

b. Disseminate Information About Apprenticeship Opportunities Through Universal Outreach and Recruitment, Including to Individuals With Disabilities

Under the 1978 Final Rule, sponsors are required to develop and maintain an affirmative action program, which requires, among other things, outreach and recruitment of women and minorities. This NPRM proposes that sponsors, in addition to contacting organizations that reach women and minorities, also contact organizations that serve individuals with disabilities. Sponsors would be required to develop a list of recruitment sources that would generate referrals from all demographic groups, including women, minorities, and individuals with disabilities, with contact information for each source. Further, sponsors would be required to notify these sources at least 30 days in advance of any apprenticeship opportunities.

We assumed that the cost to sponsors to distribute the information about apprenticeship opportunities to organizations serving individuals with disabilities will be the labor cost. We also assumed that the labor for this provision will be performed by a human resource manager and an administrative assistant with average hourly compensation rates of $68.55 and $22.28, respectively.[95]

The Department estimated that this dissemination task will take 0.5 hours of a human resource manager's time and 0.5 hours of an administrative assistant's time per targeted location. The cost of this provision per affected sponsor is, therefore, the time each staff member devotes to this task (0.5 hours for a human resource manager and 0.5 hours for an administrative assistant) multiplied by their associated average hourly compensation rates. This calculation resulted in a total labor cost of $45.41 (($68.55 × 0.5) + ($22.28 × 0.5)) per location. This total labor cost is then multiplied by the number of locations (5). The total per-entity cost for this provision for the first year is $227.05 ($45.41 × 5) for each entity.[96]

Because the universal outreach may involve several different types of activities, the Department included a sensitivity analysis on the total time allocated to universal outreach. Mirroring the sensitivity analysis calculation above in the Executive Order 12866 analysis, the Department estimated a low allocation of time (15 minutes, or 0.25 hours) and a high allocation of time (1 hour and 15 minutes, or 1.25 hours) for both the administrative assistant and the human resource manager. The resulting range of costs for the first year is $113.55 to $567.70.[97] The Department requests data from the public on how the addition of universal outreach to organizations that serve individuals with disabilities is expected to impact small entities that sponsor apprentices.

c. Disseminate Information About Apprenticeship Opportunities Through Targeted Outreach and Recruitment, Including to Individuals With Disabilities

In addition to the normal outreach, recruitment, and retention activities required of all sponsors under proposed § 30.3(b), the proposed rule would require a sponsor of an apprenticeship program, whose utilization analyses revealed underutilization of Hispanics or Latinos, women, or a particular racial minority group(s) and/or who has determined pursuant to proposed § 30.7(f) that there are problem areas with respect to its outreach, recruitment, and retention activities of individuals with disabilities, to improve and revamp their targeted outreach, as discussed in proposed § 30.8. We assume that this additional outreach will happen in the same manner as the universal outreach discussed above.

This additional outreach, recruitment, and retention would be required of sponsors who employ five or more apprentices and who are not effectively recruiting and retaining a particular underutilized group. We assume that 25 percent of all sponsors currently employ five or more apprentices, and would thus be required to develop and maintain an affirmative action program.[98] However, the Department recognizes that some sponsors may already be employing persons with disabilities as registered apprentices and, therefore, this analysis would be overestimating those who need to set goals. Unfortunately, there are no available data on the number of sponsors who are employing persons with disabilities as registered apprentices. As stated above in the discussions of proposed §§ 30.5 and 30.6, the Department requests data or information from the public on the number of sponsors who currently employ persons with disabilities.

For this analysis, we assumed that the 25 percent of all sponsors employing five or more apprentices remains constant throughout the 10-year analysis period. In reality, this percentage will fluctuate as sponsors take on new apprentices and as apprentices complete their programs. We also expect that, over time, successful outreach will lead to more hiring of persons with disabilities and that sponsors will meet their recruitment goals and not be required to complete this additional outreach.

We assumed that the cost to sponsors to distribute information about apprenticeship opportunities to organizations serving individuals with disabilities will be the labor cost. We also assumed that the labor for this provision will be performed by a human resource manager and an administrative assistant with average hourly compensation rates of $68.55 and $22.28, respectively.

The Department estimated that this dissemination task will take 0.5 hours of a human resource manager's time and 0.5 hours of an administrative assistant's time per targeted location. A sensitivity analysis for a range of time spent conducting targeted outreach to organizations that serve individuals with disabilities was conducted and is presented below. The cost of this provision per affected sponsor is, therefore, the time each staff member devotes to this task (0.5 hours for a human resource manager and 0.5 hours for an administrative assistant) multiplied by their associated average hourly compensation rates. This calculation results in a total labor cost of $45.41 (($68.55 × 0.5) + ($22.28 × 0.5)) per location. This total labor cost is then multiplied by the number of locations (5) and by the number of sponsors who sponsor 5 or more apprentices (25 percent of the total

[95] The hourly compensation rate for a human resource manager is calculated by multiplying the hourly wage of $47.94 (as published by the Department's OES survey) by 1.43 to account for private-sector employee benefits (source: BLS). Thus, the average hourly compensation rate for a human resource manager is $68.55 ($47.94 × 1.43). The average hourly compensation rate for an administrative assistant is $22.28, as calculated above.

[96] Total does not add up precisely due to rounding.

[97] To estimate the range of costs for this provision, we calculated the labor cost per affected sponsor by multiplying the time required for the task by the hourly compensation rate for both a human resource manager ($68.55 × .25 = $17.14 for the low cost and $68.55 × 1.25 = $85.69 for the high cost) and an administrative assistant ($22.28 × .25 = $5.57 for the low cost and $22.28 × 1.25 = $27.85 for the high cost). We then multiplied the total per-sponsor labor cost by the five sites for which each sponsor is to provide outreach. This results in a total cost of $113.55 for the low time assumption (($17.14 + $5.57) × 5) and $567.70 for the high time assumption (($85.69 + $27.85) × 5) in 2015.

[98] The 25 percent of sponsors who employ five or more apprenticeships was estimated from the RAPIDS data set maintained by the Department.

number of sponsors, or 5,754 (23,014 × 25 percent).

Finally, we assume that this additional outreach will occur when those sponsors who underutilize persons with disabilities are identified by the Department through audits (10 percent of the total number of sponsors). This calculation results in a total cost for this provision of approximately $238,506 annually. To estimate the cost of this provision per affected small entity, we divided this total by the estimated number of small entities (19,345), resulting in an average cost per small entity of $12.33 ($238,506/19,345). We assume that this additional outreach will occur 3 years after the rule goes into effect.

Because the targeted outreach may involve several different types of activities, the Department included a sensitivity analysis on the total time allocated to universal outreach. Mirroring the sensitivity analysis calculation above, the Department estimated a low allocation of time (15 minutes, or 0.25 hours) and a high allocation of time (1 hour and 15 minutes, or 1.25 hours) for the administrative assistant. The resulting range of costs annually is $6.17 to $30.83. The Department requests data from the public on how the targeted outreach to organizations that serve not only individuals with disabilities, but women and minorities is expected to impact small entities that sponsor apprenticeship programs.

d. Reading and Reviewing the New Regulatory Requirements

During the first year that this NPRM would be in effect, assuming that it becomes a final rule, sponsors would need to learn about the new regulatory requirements. We estimate this cost for a hypothetical small entity by multiplying the time required to read the new rule (4 hours) by the average hourly compensation rate of a human resources manager ($68.55, as calculated above). Thus, the resulting cost per small entity for this provision is $274.20 ($68.55 × 4). This cost occurs only in the year when the rule is published.

e. Orientation and Periodic Information Sessions

Proposed § 30.3(b)(2) requires each sponsor to conduct orientation and periodic information sessions for apprentices and journeyworkers who directly supervise apprentices, and other individuals connected with the administration or operation of the sponsor's apprenticeship program to inform and remind such individuals of the sponsor's equal employment opportunity policy with regard to apprenticeship.

The Department estimated a sponsor in the first year (2015) will hold one 30 minute regular orientation and periodic information sessions with on average 5 apprentices ($18.59) and 5 journeyworkers ($36.47). The Department estimated that a human resource manager ($68.55) would need to spend 4 hours to develop and prepare written materials for the session in the first year. The average annual cost over the 10-year analysis period per a small entity for this provision is $197.77.

f. Invitation to Self-Identify as an Individual With a Disability

Proposed § 30.11 requires sponsors, as part of their general duty to engage in affirmative action, to invite applicants for apprenticeship to voluntarily self-identify as an individual with a disability protected by this part at three stages: (1) At the time they apply or are considered for apprenticeship; (2) after they are accepted into the apprenticeship program but before they begin their apprenticeship; and (3) once they are enrolled in the program.

The Department estimated that a sponsor in the first year (2015) will need to develop a self-identification invitation, which must be separate from the application, for pre-offer, post-offer, and post-enrollment stages. The Department estimated that a human resource manager ($68.55) will spend 1 hour to develop a self-identification invitation and estimated that an applicant ($18.59) would take on average 5 minutes (0.083 hour) to complete the invitation. The Department also estimated that there will be an average of 10 applicants per job listings for an average for on average 5 listings per year. In addition, the Department estimated that an administrative assistant ($22.28) would spend 0.5 hour to record and keep invitations in a data analysis file. The average annual cost over the 10-year analysis period per a small entity for this provision is $117.67.

4. Total Cost Burden for Small Entities

The Department's calculations indicate that for a hypothetical small entity in the top five industry categories the average annual cost of this proposed rule is $831.02 ($2 + $227.05 + $12.33 + $274.2 + $197.77 + $117.67) + 303 + 118) The cost in the initial year is higher than the cost in subsequent years because the initial year includes the time to read and review the provisions of the new rule; costs change in the third year to reflect the additional recruitment but remain constant for the remaining years of the 10-year analysis period. Neither the entity size nor the entity sector impact the per-entity costs.

The Department also calculated a range of costs to account for some of the uncertainty in the time needed to disseminate information to underutilized groups and the time needed for universal outreach. The Department's calculations indicate that for a hypothetical small entity in the top five industry categories the annual average cost of this proposed rule is $831.02 over 2015–2024.

The total cost impacts, as a percent of revenue, are all well below the 1 percent threshold for determining a significant economic impact. The estimated cost impacts to apprenticeship sponsors for the first year, as a percent of revenue, are as follows: Construction, 0.06 percent; Manufacturing, 0.02 percent; Service, 0.1 percent; Transportation and Communication, 0.08 percent; and Trade, 0.05 percent. None of these impacts for the first year are close to 1 percent of revenues, even if considering only the high cost estimates.

Even if we measure the cost impacts, as a percent of revenue for the smallest of the small entities in each industry, they are still below the 1 percent threshold. Estimated number of sponsors classified as small entities is 9,154, 6,059, 1,936, 1,613, and 507 for construction, manufacturing, service, transportation and communication, and trade industry, respectively.

EXHIBIT 9—SUMMARY OF THE IMPACTS ON SMALL ENTITIES

Industry	Average cost as a percent of average revenue (%)	Affected small entities
1. Construction	0.06	9,154

EXHIBIT 9—SUMMARY OF THE IMPACTS ON SMALL ENTITIES—Continued

Industry	Average cost as a percent of average revenue (%)	Affected small entities
2. Manufacturing	0.02	6,059
3. Service	0.1	1,936
4. Transportation and Communication	0.08	1,613
5. Trade	0.05	507

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

The Department has reviewed this proposed rule in accordance with Executive Order 13175 and has determined that it does not have ''tribal implications.'' This NPRM does not ''have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

Executive Order 12988: Civil Justice

This NPRM has been drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform, and will not unduly burden the Federal court system. This NPRM has been written so as to minimize litigation and provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

List of Subjects in 29 CFR part 30

Administrative practice and procedure, Apprenticeship, Employment, Equal employment opportunity, Reporting and recordkeeping requirements, Training.

Signed in Washington, DC.

Portia Wu,

Assistant Secretary, Employment and Training.

For the reasons stated in the preamble, the Department of Labor proposes to amend 29 CFR parts 29 and 30 as follows:

PART 29—LABOR STANDARDS FOR THE REGISTRATION OF APPRENTICESHIP PROGRAMS

■ 1. The authority citation for part 29 continues to read as follows:

Authority: Section 1, 50 Stat. 664, as amended (29 U.S.C. 50; 40 U.S.C. 276c; 5 U.S.C. 301) Reorganization Plan No. 14 of 1950, 64 Stat. 1267 (5 U.S.C. App. P. 534).

■ 2. Amend § 29.5 by revising paragraph (b)(21) to read as follows:

§ 29.5 Standards of apprenticeship.

* * * * *

(b) * * *

(21) Compliance with 29 CFR part 30, including the equal opportunity pledge prescribed in 29 CFR 30.3(c); an affirmative action program complying with 29 CFR 30.4; and a method for the selection of apprentices complying with 29 CFR 30.10, or compliance with parallel requirements contained in a State plan for equal opportunity in apprenticeship adopted under 29 CFR part 30 and approved by the Department. The apprenticeship standards must also include a statement that the program will be conducted, operated and administered in conformity with applicable provisions of 29 CFR part 30, as amended, or if applicable, an approved State plan for equal opportunity in apprenticeship.

* * * * *

■ 3. Amend § 29.7 by revising paragraph (j) and adding paragraph (l) to read as follows:

§ 29.7 Apprenticeship agreement.

* * * * *

(j) A statement that the apprentice will be accorded equal opportunity in all phases of apprenticeship employment and training, without discrimination because of race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability.

* * * * *

(l) A request for demographic data, including the apprentice's race, sex, and ethnicity, and disability status.

■ 4. Amend § 29.8 by revising paragraph (b)(1)(i) to read as follows:

§ 29.8 Deregistration of a registered program.

* * * * *

(b) * * *

(1)(i) Deregistration proceedings may be undertaken when the apprenticeship program is not conducted, operated, or administered in accordance with the program's registered provisions or with the requirements of this part, including but not limited to: Failure to provide on-the-job learning; failure to provide related instruction; failure to pay the apprentice a progressively increasing schedule of wages consistent with the apprentices skills acquired; or persistent and significant failure to perform successfully.

* * * * *

■ 5. Amend § 29.14 by revising paragraph (a) to read as to read as follows:

§ 29.14 Derecognition of State apprenticeship agencies.

* * * * *

(a) Derecognition proceedings for failure to adopt or properly enforce a State Plan for Equal Employment Opportunity in Apprenticeship must be processed in accordance with the procedures prescribed in this part.

* * * * *

PART 30—EQUAL EMPLOYMENT OPPORTUNITY IN APPRENTICESHIP AND TRAINING

■ 6. Revise part 30 to read as follows:

PART 30—EQUAL EMPLOYMENT OPPORTUNITY IN APPRENTICESHIP

Sec.

Authority: Sec. 1, 50 Stat. 664, as amended (29 U.S.C. 50; 40 U.S.C. 276c; 5 U.S.C. 301); Reorganization Plan No. 14 of 1950, 64 Stat. 1267, 3 CFR 1949–53 Comp. p. 1007.

§ 30.1 Purpose, applicability, and relationship to other laws.

(a) *Purpose.* The purpose of this part is to promote equal opportunity for apprentices and applicants for apprenticeship in registered apprenticeship programs by prohibiting discrimination based on race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, and disability. This part also prescribes affirmative action efforts sponsors must take to ensure equal opportunity for apprentices and applicants for apprenticeship. The regulations set forth the equal opportunity obligations of sponsors, the contents of affirmative action programs, procedures for the filing and processing of complaints, and enforcement procedures. These regulations also establish procedures for deregistration of an apprenticeship program in the event of noncompliance with this part and prescribe the equal opportunity requirements for recognition of State Apprenticeship Agencies (SAA) under part 29.

(b) *Applicability.* This part applies to all sponsors of apprenticeship programs registered with either the U.S. Department of Labor or a recognized SAA.

(c) *Relationship to other laws.* This part does not invalidate or limit the remedies, rights, and procedures under any Federal law or the law of any State or political subdivision of any State or jurisdiction that provides greater or equal protection for individuals based on race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability than are afforded by this part. It may be a defense to a charge of a violation of this part that a challenged action is required or necessitated by another Federal law or regulation, or that another Federal law or regulation prohibits an action that would otherwise be required by this part.

§ 30.2 Definitions.

For the purpose of this part:

Administrator means the Administrator of the Office of Apprenticeship, or any person specifically designated by the Administrator.

Apprentice means a worker at least 16 years of age, except where a higher minimum age standard is otherwise fixed by law, who is employed to learn an apprenticeable occupation as provided in § 29.4 of this title under standards of apprenticeship fulfilling the requirements of § 29.5 of this title.

Apprenticeship Committee (Committee) means those persons designated by the sponsor to administer the program. A committee may be either joint or non-joint, as follows:

(1) A joint committee is composed of an equal number of representatives of the employer(s) and of the employees represented by a bona fide collective bargaining agent(s).

(2) A non-joint committee, which may also be known as a unilateral or group non-joint (which may include employees) committee, has employer representatives but does not have a bona fide collective bargaining agent as a participant.

Apprenticeship program means a plan containing all terms and conditions for the qualification, recruitment, selection, employment and training of apprentices, as required under 29 CFR parts 29 and 30, including such matters as the requirement for a written apprenticeship agreement.

Department means the U.S. Department of Labor.

Direct threat means a significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation. The determination that an individual poses a ''direct threat'' must be based on an individualized assessment of the individual's present ability to safely perform the essential functions of the job. This assessment must be based on a reasonable medical judgment that relies on the most current medical knowledge and/or on the best available objective evidence. In determining whether an individual would pose a direct threat, the factors to be considered include:

(1) The duration of the risk;

(2) The nature and severity of the potential harm;

(3) The likelihood that the potential harm will occur; and

(4) The imminence of the potential harm.

Disability [1] means, with respect to an individual:

(1) A physical or mental impairment that substantially limits one or more major life activities of such individual;

(2) A record of such an impairment; or

(3) Being regarded as having such an impairment.

EEO means equal employment opportunity.

Electronic media means media that utilize electronics or electromechanical energy for the end user (audience) to access the content; and includes, but is not limited to, electronic storage media, transmission media, the Internet, extranet, lease lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic media and/or interactive distance learning.

Employer means any person or organization employing an apprentice whether or not such person or organization is a party to an Apprenticeship Agreement with the apprentice.

Ethnicity, for purposes of recordkeeping and affirmative action, has the same meaning as under the Office of Management and Budget's Standards for the Classification of Federal Data on Race and Ethnicity, 62 FR 58782 (Oct. 30, 1997), or any successor standards. Ethnicity thus refers to the following designations:

(1) Hispanic or Latino—A person of Cuban, Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race.

(2) Not Hispanic or Latino

Genetic information means:

(1) Information about:

(i) An individual's genetic tests;

(ii) The genetic tests of that individual's family members;

(iii) The manifestation of disease or disorder in family members of the individual (family medical history);

(iv) An individual's request for, or receipt of, genetic services, or the participation in clinical research that includes genetic services by the individual or a family member of the individual; or

(v) The genetic information of a fetus carried by an individual or by a pregnant woman who is a family member of the individual and the genetic information of any embryo legally held by the individual or family member using an assisted reproductive technology.

(2) Genetic information does not include information about the sex or age

[1] The definitions for the term ''disability'' and other terms relevant to defining disability and disability discrimination standards, including ''direct threat'', ''major life activities'', ''physical or mental impairment'', ''qualified applicant or apprentice'', ''reasonable accommodation'', and ''undue hardship, are taken directly from title I of the Americans with Disabilities Act (ADA), as amended by the Americans with Disabilities Act Amendments Act (ADAAA) and from the Equal Employment Opportunity Commission's regulations implementing the ADA at 29 CFR part 1630, to the extent that the ADAAA did not provide a definition.

of the individual, the sex or age of family members, or information about the race or ethnicity of the individual or family members that is not derived from a genetic test.[2]

Journeyworker means a worker who has attained a level of skill, abilities and competencies recognized within an industry as having mastered the skills and competencies required for the occupation. (Use of the term may also refer to a mentor, technician, specialist or other skilled worker who has documented sufficient skills and knowledge of an occupation, either through formal apprenticeship or through practical on-the-job experience and formal training.)

Major life activities include, but are not limited to: Caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, sitting, reaching, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, interacting with others, and working. A major life activity also includes the operation of a major bodily function, including but not limited to, functions of the immune system, special sense organs and skin; normal cell growth; and digestive, genitourinary, bowel, bladder, neurological, brain, respiratory, circulatory, cardiovascular, endocrine, hemic, lymphatic, musculoskeletal, and reproductive functions. The operation of a major bodily function includes the operation of an individual organ within a body system.

Office of Apprenticeship (OA) means the office designated by the Employment and Training Administration of the U.S. Department of Labor to administer the National Registered Apprenticeship System or its successor organization.

Physical or mental impairment means:

(1) Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more body systems, such as neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, immune, circulatory, hemic, lymphatic, skin, and endocrine; or

(2) Any mental or psychological disorder, such as intellectual disability (formerly termed ''mental retardation''), organic brain syndrome, emotional or mental illness, and specific learning disabilities.

Pre-apprenticeship program means a training model designed to assist individuals who do not currently possess the minimum requirements for selection into an apprenticeship program to meet the minimum selection criteria established in a program sponsor's apprenticeship standards required under part 29. It involves a form of structured workplace education and training in which an employer, employer group, industry association, labor union, community-based organization, or educational institution collaborates to provide formal instruction that will introduce participants to the competencies, skills, and materials used in one or more apprenticeable occupations. It may also involve provision of supportive services such as transportation, child care, and income support to assist participants in the successful completion of the pre-apprenticeship program.

Qualified applicant or apprentice is an individual who, with or without reasonable accommodation, can perform the essential functions of the apprenticeship program for which the individual applied or is enrolled.

Race, for purposes of recordkeeping and affirmative action, has the same meaning as under the Office of Management and Budget's Standards for the Classification of Federal Data on Race and Ethnicity, 62 FR 58782 (Oct. 30, 1997), or any successor standards. Race thus refers to the following designations:

(1) White—A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

(2) Black or African American—A person having origins in any of the black racial groups of Africa.

(3) Native Hawaiian or Other Pacific Islander—A person having origins in any of the peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

(4) Asian—A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian Subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

(5) American Indian or Alaska Native—A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.

Reasonable accommodation (1) The term *reasonable accommodation* means:

(i) Modifications or adjustments to a job application process that enable a qualified applicant with a disability to be considered for the position such qualified applicant desires; or

(ii) Modifications or adjustments to the work environment, or to the manner or circumstances under which the position held or desired is customarily performed, that enable a qualified individual with a disability to perform the essential functions of that position; or

(iii) Modifications or adjustments that enable a sponsor's apprentice with a disability to enjoy equal benefits and privileges of apprenticeship as are enjoyed by its other similarly situated apprentices without disabilities.

(2) *Reasonable accommodation* may include but is not limited to:

(i) Making existing facilities used by apprentices readily accessible to and usable by individuals with disabilities; and

(ii) Job restructuring; part-time or modified work schedules; reassignment to a vacant position; acquisition or modifications of equipment or devices; appropriate adjustment or modifications of examinations, training materials, or policies; the provision of qualified readers or interpreters; and other similar accommodations for individuals with disabilities.

(3) To determine the appropriate reasonable accommodation it may be necessary for the sponsor to initiate an informal, interactive process with the qualified individual in need of the accommodation. This process should identify the precise limitations resulting from the disability and potential reasonable accommodations that could overcome those limitations.

Registration Agency means the Office of Apprenticeship or a recognized SAA that has responsibility for registering apprenticeship programs and apprentices; providing technical assistance; conducting quality assurance assessments and reviews of registered apprenticeship programs for compliance with the requirements of part 29 and this part.

Selection procedure means any measure, combination of measures, or procedure used as a basis for any decision in apprenticeship. Selection procedures include the full range of assessment techniques from traditional paper and pencil tests, performance tests, training programs, or probationary periods and physical, educational, and work experience requirements through informal or casual interviews and unscored application forms.

Sponsor means any person, association, committee or organization operating an apprenticeship program, and in whose name the program is (or is to be) registered or approved.

[2] The definition of the term ''genetic information'' is taken directly from the Genetic Information Nondiscrimination Act of 2008 (GINA) at 42 U.S.C. 2000ff(4) and the EEOC's implementing regulations at 29 CFR 1635.3(c).

State Apprenticeship Agency (SAA) means an agency of a State government that has responsibility and accountability for apprenticeship within the State. Only an SAA may seek recognition from OA as an agency which has been properly constituted under an acceptable law or Executive Order (E.O.), and authorized by OA to register and oversee apprenticeship programs and agreements for Federal purposes.

Undue hardship—(1) *In general.* Undue hardship means, with respect to the provision of an accommodation, significant difficulty or expense incurred by a sponsor, when considered in light of the factors set forth in paragraph (2) of this definition.

(2) *Factors to be considered.* In determining whether an accommodation would impose an undue hardship on a sponsor, factors to be considered include:

(i) The nature and net cost of the accommodation needed under this part, taking into consideration the availability of tax credits and deductions, and/or outside funding;

(ii) The overall financial resources of the facility or facilities involved in the provision of the reasonable accommodation, the number of persons employed at such facility, and the effect on expenses and resources;

(iii) The overall financial resources of the sponsor, the overall size of the registered apprenticeship program with respect to the number of apprentices, and the number, type and location of its facilities;

(iv) The type of operation or operations of the sponsor, including the composition, structure and functions of the workforce of such entity, and the geographic separateness and administrative or fiscal relationship of the facility or facilities in question to the sponsor; and

(v) The impact of the accommodation upon the operation of the facility, including the impact on the ability of other apprentices to perform their duties and the impact on the facility's ability to conduct business.

§ 30.3 Equal opportunity standards applicable to all sponsors.

(a) *Discrimination prohibited.* (1) It is unlawful for a sponsor of a registered apprenticeship program to discriminate against an apprentice or applicant for apprenticeship on the basis of race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability with regard to:

(i) Recruitment, outreach, and selection procedures;

(ii) Hiring, upgrading, periodic advancement, promotion, award of tenure, demotion, transfer, layoff, termination, right of return from layoff, and rehiring;

(iii) Rotation among work processes;

(iv) Imposition of penalties or other disciplinary action;

(v) Rates of pay or any other form of compensation and changes in compensation;

(vi) Conditions of work;

(vii) Hours of work and hours of training provided;

(viii) Job assignments;

(ix) Leaves of absence, sick leave, or any other leave; and

(x) Any other benefit, term, condition, or privilege associated with apprenticeship.

(2) *Discrimination standards and defenses*—(i) *Race, color, religion, national origin, sex, or sexual orientation.* In implementing this section, the Registration Agency will apply the same legal standards and defenses as those applied under title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq.,* in determining whether a sponsor has engaged in an unlawful employment practice.

(ii) *Disability.* With respect to discrimination based on a disability, the Registration Agency will apply the same standards, defenses, and exceptions to the definition of disability as those set forth in title I of the Americans with Disabilities Act (ADA), 42 U.S.C. 12112 and 12113, and the implementing regulations promulgated by the Equal Employment Opportunity Commission (EEOC) at 29 CFR part 1630, which include, among other things, the standards governing reasonable accommodation, medical examinations and disability-related inquiries, qualification standards, and direct threat defense. The Interpretive Guidance on title I of the ADA set out as an appendix to part 1630 issued pursuant to title I may be relied upon for guidance in complying with the nondiscrimination requirements of this part with respect to the treatment of individuals with disabilities.

(iii) *Age.* The Registration Agency will apply the same standards and defenses for age discrimination as those set forth in the Age Discrimination in Employment Act (ADEA), 29 U.S.C. 623, and the implementing regulations promulgated by the EEOC at 29 CFR part 1625.

(iii) *Genetic information.* The Registration will apply the same standards and defenses for discrimination based on genetic information as those set forth in the Genetic Information Nondiscrimination Act (GINA), 29 U.S.C. 2000ff *et seq.,* and the implementing regulations promulgated by the EEOC at 29 CFR part 1635.

(b) *General duty to engage in affirmative action.* For each registered apprenticeship program, a sponsor is required to take affirmative steps to provide equal opportunity in apprenticeship. These steps must include:

(1) *Assignment of responsibility.* The sponsor will designate an individual with appropriate authority under the program, such as an apprenticeship coordinator, to be responsible and accountable for overseeing its commitment to equal opportunity in registered apprenticeship, including the development and implementation of an affirmative action program as required by § 30.4. This individual must have the resources, support of, and access to the sponsor leadership to ensure effective implementation. This individual will be responsible for:

(i) Monitoring all registered apprenticeship activity to ensure compliance with the nondiscrimination and affirmative action obligations required by this part;

(ii) Maintaining records required under this part; and

(iii) Generating and submitting reports as may be required by the Registration Agency.

(2) *Internal dissemination of equal opportunity policy.* The sponsor must inform all applicants for apprenticeship, apprentices, and individuals who operate or administer any aspect of the registered apprenticeship program of its commitment to equal opportunity and its affirmative action obligations. In addition, the sponsor must require that individuals connected with the administration or operation of the apprenticeship program take the necessary action to aid the sponsor in meeting its nondiscrimination and affirmative action obligations under this part. A sponsor, at a minimum, is required to:

(i) Publish its equal opportunity pledge required in paragraph (c) of this section in the apprenticeship standards required under § 29.5 of this title, and in appropriate publications, such as apprentice and employee handbooks, policy manuals, newsletters, and other appropriate publications;

(ii) Post its equal opportunity pledge from paragraph (c) of this section on bulletin boards, including through electronic media, such that it is accessible to all apprentices and applicants for apprenticeship;

(iii) Conduct orientation and periodic information sessions for apprentices,

journeyworkers who directly supervise apprentices, and other individuals connected with the administration or operation of the sponsor's apprenticeship program to inform and remind such individuals of the sponsor's equal employment opportunity policy with regard to apprenticeship; and

(iv) Maintain records necessary to demonstrate compliance with these requirements and make them available to the Registration Agency upon request.

(3) *Universal outreach and recruitment.* The sponsor will implement measures to ensure that its outreach and recruitment efforts for apprentices extend to all persons available for apprenticeship within the sponsor's relevant recruitment area without regard to race, sex, ethnicity, or disability. In furtherance of this requirement, the sponsor must:

(i) Develop and update annually a list of current recruitment sources that will generate referrals from all demographic groups within the relevant recruitment area. Examples of relevant recruitment sources include: The public workforce system's One-Stop Career Centers and local workforce investment boards; community-based organizations; community colleges; vocational, career and technical schools; pre-apprenticeship programs; and Federally-funded, youth job-training programs such as YouthBuild and Job Corps or their successors;

(ii) Identify a contact person, mailing address, telephone number, and email address for each recruitment source; and

(iii) Provide recruitment sources advance notice, preferably 30 days, of apprenticeship openings so that the recruitment sources can notify and refer candidates. Such notification must also include documentation of the sponsor's equal opportunity pledge specified in paragraph (c) of this section.

(4) *Maintain workplace free from harassment, intimidation, and retaliation.* The sponsor must develop and implement procedures to ensure that its apprentices are not harassed because of their race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability and to ensure that its workplace is free from intimidation and retaliation as prohibited by § 30.16. To ensure an environment in which all apprentices feel safe, welcomed, and treated fairly, the sponsor must:

(i) Communicate to all personnel that harassing conduct will not be tolerated;

(ii) Provide anti-harassment training to all personnel;

(iii) Make all facilities and apprenticeship activities available without regard to race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability except that if the sponsor provides restrooms or changing facilities, the sponsor must provide separate or single-user restrooms and changing facilities to assure privacy between the sexes;

(iv) Establish and implement procedures for handling and resolving complaints about harassment and intimidation based on race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, and disability.

(5) *Compliance with Federal and State equal employment opportunity laws.* The sponsor (or where the sponsor is a joint apprenticeship committee, parties represented on such committee) must comply with all applicable Federal and State laws and regulations requiring equal employment opportunity without regard to race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability. Failure to comply with such laws is grounds for deregistration or the imposition of other enforcement actions in accordance with § 30.14.

(c) *Equal opportunity pledge.* Each sponsor of an apprenticeship program must include in its Standards of Apprenticeship and apprenticeship opportunity announcements the following equal opportunity pledge:

> [Name of sponsor] will not discriminate against apprenticeship applicants or apprentices based on race, color, religion, national origin, sex (including pregnancy and gender identity), sexual orientation, genetic information, or because they are an individual with a disability or a person 40 years old or older. [Name of sponsor] will take affirmative action to provide equal opportunity in apprenticeship and will operate the apprenticeship program as required under Title 29 of the Code of Federal Regulations, part 30.

The nondiscrimination bases listed in this pledge may be broadened to conform to consistent State and local requirements. Sponsors may include additional protected bases but may not exclude any of the bases protected by this part.

§ 30.4 Affirmative action programs.

(a) *Definition and purpose.* As used in this part: (1) An affirmative action program is designed to ensure equal opportunity and prevent discrimination in apprenticeship programs. An affirmative action program is more than mere passive nondiscrimination. Such a program requires the sponsor to take affirmative steps to encourage and promote equal opportunity, to create an environment free from discrimination, and to address any barriers to equal opportunity in apprenticeship. An affirmative action program is more than a paperwork exercise. It includes those policies, practices, and procedures, including self analyses, that the sponsor implements to ensure that all qualified applicants and apprentices are receiving an equal opportunity for recruitment, selection, advancement, retention and every other term and privilege associated with apprenticeship. An affirmative action program should be a part of the way the sponsor regularly conducts its apprenticeship program.

(2) A central premise underlying affirmative action is that, absent discrimination, over time a sponsor's apprenticeship program, generally, will reflect the sex, race, ethnicity, and disability profile of the labor pools from which the sponsor recruits and selects. Consistent with this premise, affirmative action programs contain a diagnostic component which includes quantitative analyses designed to evaluate the composition of the sponsor's apprenticeship program and compare it to the composition of the relevant labor pools. If women, individuals with disabilities, or individuals from a particular minority group, for example, are not being admitted into apprenticeship at a rate to be expected given their availability in the relevant labor pool, the sponsor's affirmative action program must include specific, practical steps designed to address any barriers to equal opportunity that may be contributing to this underutilization.

(3) Effective affirmative action programs include internal auditing and reporting systems as a means of measuring the sponsor's progress toward achieving an apprenticeship program that would be expected absent discrimination.

(4) An affirmative action program also ensures equal opportunity in apprenticeship by incorporating the sponsor's commitment to equality in every aspect of the apprenticeship program. Therefore, as part of its affirmative action program, a sponsor must monitor and examine its employment practices, policies and decisions and evaluate the impact such practices, policies and decisions have on the recruitment, selection and advancement of apprentices. It must evaluate the impact of its employment and personnel policies on minorities, women, and persons with disabilities, and revise such policies accordingly where such policies or practices are found to create a barrier to equal opportunity.

(5) The commitments contained in an affirmative action program are not intended and must not be used to discriminate against any qualified applicant or apprentice on the basis of race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability.

(b) *Adoption of affirmative action programs.* Sponsors other than those identified in paragraph (d) of this section must develop and maintain an affirmative action program, setting forth that program in a written plan in the timeframe provided by § 30.20 of this part. The written plan must be made available to the Registration Agency any time thereafter upon request.

(c) *Contents of affirmative action programs.* An affirmative action program must include the following components in addition to those required of all sponsors by § 30.3(a):

(1) Utilization analysis for race, sex, and ethnicity, as described in § 30.5;

(2) Establishment of utilization goals for race, sex, and ethnicity, as described in § 30.6;

(3) Utilization goals for individuals with disabilities, as described in § 30.7;

(4) Targeted outreach, recruitment, and retention, as described in § 30.8; and

(5) Review of personnel processes, as described in § 30.9

(d) *Exemptions*—(1) *Programs with fewer than five apprentices.* A sponsor is exempt from the requirements of paragraph (b) of this section if the sponsor's apprenticeship program has fewer than five apprentices registered, unless such program was adopted to circumvent the requirements of this section.

(2) *Programs subject to approved equal employment opportunity programs.* A sponsor is exempt from the requirements of paragraph (b) of this section if the sponsor both submits to the Registration Agency satisfactory evidence that it is in compliance with an equal employment opportunity program providing for affirmative action in apprenticeship, including the use of goals for any underrepresented group or groups of individuals, which has been approved as meeting the requirements of either title VII of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000e *et seq.*) and agrees to extend such program to include individuals with disabilities, or if the sponsor submits to the Registration Agency satisfactory evidence that it is in compliance with an equal employment opportunity program providing for affirmative action in apprenticeship, including the use of goals for any underrepresented group or groups of individuals, which has been approved as meeting the requirements of both Executive Order 11246, as amended, and section 503 of the Rehabilitation Act, as amended (29 U.S.C. 793), and their implementing regulations at title 41 of the Code of Federal Regulations, chapter 60:

Provided, That programs approved, modified or renewed subsequent to the effective date of this amendment will qualify for this exception only if the goals for any underrepresented group for the selection of apprentices provided for in such programs are equal to or greater than the goals required under this part.

(e) *Review of affirmative action programs.* Sponsors are required to internally review all elements of their affirmative action programs on an annual basis. If, however, a sponsor's annual review demonstrates that there is no underutilization in any industry within the sponsor's program and that the sponsor's review of its personnel practices, pursuant to § 30.9, did not indicate any necessary modifications, then the sponsor may wait two years to complete its next affirmative action program review. Qualifying for this extended review period does not change any other obligations set forth in these regulations.

§ 30.5 Utilization analysis for race, sex, and ethnicity.

(a) *Purpose.* The purpose of the utilization analysis is to provide sponsors with a method for assessing whether possible barriers to apprenticeship exist for particular groups of individuals by determining whether the race, sex, and ethnicity for apprentices in a sponsor's apprenticeship program is reflective of persons available for apprenticeship by race, sex, and ethnicity in the relevant recruitment area. Where significant disparity exists between availability and representation in the sponsor's apprenticeship program, the sponsor will be required to establish a utilization goal pursuant to § 30.6.

(b) *Analysis of apprenticeship program workforce.* Sponsors must analyze the racial, sex, and ethnic composition of their apprentice workforce. This is a two-step process. First, each sponsor must group all occupational titles represented in its registered apprenticeship program by industry. Next, for each industry represented, the sponsor must identify the race, sex, and ethnicity of its apprentices within that industry.

(c) *Availability analysis*—(1) *Purpose.* The purpose of the availability analysis is to establish a benchmark against which the demographic composition of the sponsor's apprenticeship program can be compared in order to determine whether barriers to equal opportunity may exist with regard to the sponsor's apprenticeship program.

(2) Availability is an estimate of the number of qualified individuals available for apprenticeship by race, sex, and ethnicity expressed as a percentage of all qualified persons available for apprenticeship in the sponsor's relevant recruitment area.

(3) In determining availability, the sponsor must consider at least the following factors for each occupational title represented in the sponsor's registered apprenticeship program standards:

(i) The percentage of individuals available with the present or potential capacity for apprenticeship in the sponsor's relevant recruitment area broken down by race, sex, and ethnicity; and

(ii) The percentage of the sponsor's employees with the present or potential capacity for apprenticeship broken down by race, sex, and ethnicity.

(4) In determining availability, the relevant recruitment area is defined as the geographical area from which the sponsor usually seeks or reasonably could seek apprentices. The sponsor must identify the relevant recruitment area in its written affirmative action plan (AAP). The sponsor may not draw its relevant recruitment area in such a way as to have the effect of excluding individuals based on race, sex, or ethnicity from consideration, and must develop a brief rationale for selection of that recruitment area.

(5) The sponsor must use the most current and discrete statistical information available to derive availability figures. The sponsor should consult the Bureau of Labor Statistics' Occupational Handbook to confirm the educational background required for the particular occupation. The sponsor should then consult sources such as the American Community Survey for data on the size of the eligible population in the relevant recruitment area with the appropriate educational attainment for entrance into the apprenticeship program. Examples of such data include but are not limited to data from the Census Bureau's American Community Survey; the Census Bureau's EEO Data Tool currently available at *http://www.census.gov/people/eeotabulation/data/eeotables20062010.html*; the Census Bureau's Quick Facts tables currently available at *http://quickfacts.census.gov*; labor market information data from State workforce agencies; data from vocational education schools, secondary and post-secondary school or other

career and employment training institutions; educational attainment data from the Census Bureau; and for sponsors of registered apprenticeship programs in the construction industry, any data provided by the Department's Office of Federal Contract Compliance Program (OFCCP) through their regulations at 41 CFR part 60–4, Construction Contractors—Affirmative Action Requirements or otherwise.

(d) *Rate of utilization.* Based on the apprentice workforce analysis performed in paragraph (b) of this section and the availability analysis performed in paragraph (c) of this section, when the sponsor's utilization of women, Hispanics or Latinos, or a particular racial minority group in its apprenticeship program is less than would be reasonably expected given the availability of such individuals for apprenticeship, the sponsor must establish a utilization goal for the affected group in accordance with the procedures set forth in § 30.6. Sponsors are not required or expected to establish goals where no disparity in utilization rates has been found.

§ 30.6 Establishment of utilization goals for race, sex, and ethnicity.

(a) Where, pursuant to § 30.5, a sponsor is required to establish a utilization goal for a particular group in its apprenticeship program, the sponsor must establish a percentage goal at least equal to the availability figure derived under § 30.5(c).

(b) A sponsor's determination under § 30.5 that a utilization goal is required constitutes neither a finding nor an admission of discrimination.

(c) Utilization goals serve as objectives or targets reasonably attainable by means of applying every good faith effort to make all aspects of the entire affirmative action program work. Utilization goals are used to measure the effectiveness of the sponsor's outreach, recruitment, and retention efforts.

(d) In establishing utilization goals, the following principles apply:

(1) Utilization goals may not be rigid and inflexible quotas, which must be met, nor are they to be considered either a ceiling or a floor for the selection of particular groups as apprentices. Quotas are expressly forbidden.

(2) Utilization goals may not provide a sponsor with a justification to extend a preference to any individual, select an individual, or adversely affect an individual's status as an apprentice, on the basis of that person's race, sex, or ethnicity.

(3) Utilization goals do not create set-asides for specific groups, nor are they intended to achieve proportional representation or equal results; rather they are intended to assist with identifying the existence of barriers to equal opportunity.

(4) Utilization goals may not be used to supersede eligibility requirements for apprenticeship. Affirmative action programs prescribed by the regulations of this part do not require sponsors to select a person who lacks qualifications to participate in the apprenticeship program successfully, or select a less-qualified person in preference to a more qualified one.

§ 30.7 Utilization goals for individuals with disabilities.

(a) *Utilization goal.* The Administrator of OA has established a utilization goal of 7 percent for employment of qualified individuals with disabilities as apprentices for each industry within which the sponsor has an apprenticeship program.

(b) *Purpose.* The purpose of the utilization goal established in paragraph (a) of this section is to establish a benchmark against which the sponsor must measure the representation of individuals with disabilities in the sponsor's apprentice workforce by industry in order to assess whether any barriers to equal opportunity in apprenticeship remain. The goal serves as an equal opportunity objective that should be attainable by complying with all of the affirmative action requirements of this part.

(c) *Periodic review of goal.* The Administrator of OA will periodically review and update, as appropriate, the utilization goal established in paragraph (a) of this section.

(d) *Utilization analysis*—(1) *Purpose.* The utilization analysis is designed to evaluate the representation of individuals with disabilities in the sponsor's apprentice workforce grouped by industry. If individuals with disabilities are represented in the sponsor's apprentice workforce in any given industry at a rate less than the utilization goal, the sponsor must take specific measures to address this disparity.

(2) *Apprentice workforce analysis.* Sponsors are required to analyze the representation of individuals with disabilities within their apprentice workforce by industry. This is a two-step process. First, as required in § 30.5, each sponsor must group all occupational titles represented in its registered apprenticeship program by industry. Next, for each industry represented, the sponsor must identify the number of apprentices with disabilities.

(3) *Schedule of evaluation.* The sponsor must evaluate its utilization of apprentices with disabilities in each group identified in paragraph (d)(2) of this section annually, or biannually if it meets the conditions for biannual review set forth in § 30.4(e) of this part.

(e) *Identification of problem areas.* When the percentage of individuals with disabilities in one or more industries within which a sponsor has apprentices is less than the utilization goal established in paragraph (a) of this section, the sponsor must take steps to determine whether and where impediments to equal opportunity exist. When making this determination, the sponsor must look at the results of its assessment of personnel processes and the effectiveness of its outreach and recruitment efforts required by § 30.9.

(f) *Action-oriented programs.* The sponsor must undertake action oriented programs, including targeted outreach, recruitment, and retention activities identified in § 30.8, designed to correct any problem areas that the sponsor identified pursuant to its review of personnel processes and outreach and recruitment efforts.

(g) A sponsor's determination that it has not attained the utilization goal established in paragraph (a) of this section in one or more industry groups does not constitute either a finding or admission of discrimination in violation of this part.

(h) The utilization goal established in paragraph (a) of this section must not be used as a quota or ceiling that limits or restricts the employment of individuals with disabilities as apprentices.

§ 30.8 Targeted outreach, recruitment, and retention.

(a) *Minimum activities* required. Where a sponsor has found underutilization and established a utilization goal for a specific group or groups pursuant to § 30.6, and/or where a sponsor has determined pursuant to § 30.7(f) that there are problem areas with respect to its outreach, recruitment, and retention activities for individuals with disabilities, the sponsor must undertake targeted outreach, recruitment, and retention activities that are likely to generate an increase in applications for apprenticeship from and improve retention of apprentices from the targeted group or groups and/or from individuals with disabilities, as appropriate. In furtherance of this requirement, the sponsor must:

(1) Set forth in its written AAP the specific targeted outreach, recruitment, and retention activities it plans to take

for the upcoming program year. Such activities must include at a minimum:

(i) Dissemination of information to community-based organizations, local high schools, local community colleges, local vocational, career and technical schools, and other groups serving the underutilized group regarding the nature of apprenticeship, requirements for selection for apprenticeship, availability of apprenticeship opportunities, and the equal opportunity pledge of the sponsor;

(ii) Advertising openings for apprenticeship opportunities by publishing advertisements in newspapers and other media, electronic or otherwise, which have wide circulation in the relevant recruitment areas;

(iii) Cooperation with local school boards and vocational education systems to develop and/or establish relationships with pre-apprenticeship programs targeting students from the underutilized group to prepare them to meet the standards and criteria required to qualify for entry into apprenticeship programs; and

(iv) Establishment of linkage agreements enlisting the assistance and support of pre-apprenticeship programs, community-based organizations and advocacy organizations in recruiting qualified individuals for apprenticeship and in developing pre-apprenticeship programs.;

(2) Evaluate and document after every selection cycle for registering apprentices the overall effectiveness of such activities;

(3) Refine its targeted outreach, recruitment, and retention activities as needed; and

(4) Maintain records of its targeted outreach, recruitment, and retention activities and records related to its evaluation of these activities.

(b) *Other activities.* In addition to the activities set forth in paragraph (a) of this section, as a matter of best practice, sponsors are encouraged but not required to consider other outreach, recruitment, and retention activities that may assist sponsors in addressing any barriers to equal opportunity in apprenticeship. Such activities include but are not limited to:

(1) Enlisting the use of journeyworkers from the underutilized group or groups to assist in the implementation of the sponsor's affirmative action program;

(2) Enlisting the use of journeyworkers from the underutilized group or groups to mentor apprentices and to assist with the sponsor's targeted outreach and recruitment activities; and

(3) Conducting exit interviews of each apprentice who leaves the sponsor's apprenticeship program prior to receiving a certificate of completion to understand better why the apprentice is leaving the program and to help shape the sponsor's retention activities.

§ 30.9 Review of personnel processes.

(a) As part of its affirmative action program, the sponsor must, for each registered apprenticeship program, engage in an annual review of its personnel processes related to the administration of the apprenticeship program to ensure that the sponsor is operating an apprenticeship program free from discrimination based on race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, and disability. The review must be a careful, thorough, and systematic one and include review of all aspects of the apprenticeship program, including but not limited to the qualifications for apprenticeship, application and selection procedures, wages, outreach and recruitment activities, advancement opportunities, promotions, work assignments, job performance, rotations among all work processes of the occupation, disciplinary actions, handling of requests for reasonable accommodations, and the program's accessibility to individuals with disabilities (including to the use of information and communication technology). The sponsor must make any necessary modifications to its program to ensure that its obligations under this part are met.

(b) The sponsor must include a description of its review in its written AAP and identify in the written plan any modifications made or to be made to the program as a result of its review.

§ 30.10 Selection of apprentices.

(a) A sponsor's procedures for selection of apprentices must be included in the written plan for Standards of Apprenticeship submitted to and approved by the Registration Agency, as required under § 29.5 of this title.

(b) Sponsors may utilize any method for selection of apprentices, provided that the selection method used meets the following requirements:

(1) The use of the selection procedure must comply with the Uniform Guidelines on Employee Selection Procedures (UGESP) (41 CFR part 60–3), including the requirements to evaluate the impact of the selection procedure on race, sex, and ethnic groups (Hispanic or Latino/non-Hispanic or Latino) and to demonstrate job-relatedness and business necessity for those procedures that result in adverse impact in accordance with the requirements of UGESP.

(2) The selection procedure must be uniformly and consistently applied to all applicants and apprentices.

(3) The selection procedure must comply with title I of the ADA and EEOC's implementing regulations at part 1630. This procedure must not screen out or tend to screen out an individual with a disability or a class of individuals with disabilities, on the basis of disability, unless the standard, test or other selection criteria, as used by the program sponsor, is shown to be job-related for the position in question and is consistent with business necessity.

(4) The selection procedure must be facially neutral in terms of race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, and disability.

§ 30.11 Invitation to self-identify as an individual with a disability—(a) Pre-offer.

(1) As part of the sponsor's general duty to engage in affirmative action, the sponsor must invite applicants for apprenticeship to inform the sponsor whether the applicant believes that that he or she is an individual with a disability as defined in § 30.2. This invitation must be provided to each applicant when the applicant applies or is considered for apprenticeship. The invitation may be included with the application materials for apprenticeship, but must be separate from the application.

(2) The sponsor must invite an applicant to self-identify as required in paragraph (a) of this section using the language and manner prescribed by the Administrator and published on the OA Web site.

(b) *Post offer.* (1) At any time after acceptance into the apprenticeship program, but before the applicant begins his or her apprenticeship, the sponsor must invite the applicant to inform the sponsor whether the applicant believes that he or she is an individual with a disability as defined in § 30.2.

(1) The sponsor must invite an applicant to self-identify as required in paragraph (b) of this section using the language and manner prescribed by the Administrator and published on the OA Web site.

(c) *Apprentices.* The sponsor must invite each of its apprentices to voluntarily inform the sponsor whether the apprentice believes that he or she is an individual with a disability as defined in § 30.2. This invitation shall be extended the first year the sponsor

becomes subject to the requirements of this section and then each time an apprentice is enrolled into an apprenticeship program. The sponsor must remind apprentices yearly that they may voluntarily update their disability status.

(d) The sponsor may not compel or coerce an individual to self-identify as an individual with a disability.

(e) The sponsor must keep all information on self-identification confidential, and must maintain it in a data analysis file (rather than the medical files of individual apprentices). *See* § 30.12(e). The sponsor must provide self-identification information to the Registration Agency upon request. Self-identification information may be used only in accordance with this part.

(f) Nothing in this section may relieve the sponsor of its obligation to take affirmative action with respect to those applicants and apprentices of whose disability the sponsor has knowledge.

(g) Nothing in this section may relieve the sponsor from liability for discrimination in violation of this part.

§ 30.12 Recordkeeping.

(a) *General obligation.* Each sponsor must collect such data and maintain such records as the Registration Agency finds necessary to determine whether the sponsor has complied or is complying with the requirements of this part. Such records must include, but are not limited to records relating to:

(1) Selection for apprenticeship, including applications, tests and test results, interview notes, bases for selection or rejection, and any other records required to be maintained under UGESP;

(2) The invitation to self-identify as an individual with a disability;

(3) Information relative to the operation of the apprenticeship program, including but not limited to job assignments in all components of the occupation as required under § 29.5(b)(3) of this title, promotion, demotion, transfer, layoff, termination, rates of pay, other forms of compensation, conditions of work, hours of work, hours of training provided, and any other personnel records relevant to EEO complaints filed with the Registration Agency under § 30.14 or with other enforcement agencies;

(4) Compliance with the requirements of § 30.3;

(5) Requests for reasonable accommodation; and

(6) Any other records pertinent to a determination of compliance with these regulations, as may be required by the Registration Agency.

(b) *Sponsor identification of record.* For any record the sponsor maintains pursuant to this part, the sponsor must be able to identify the race, sex, ethnicity (Hispanic or Latino/non-Hispanic or Latino), and when known, disability status of each apprentice, and where possible, the race, sex, ethnicity, and disability status of each applicant to apprenticeship and supply this information upon request to the Registration Agency.

(c) *Affirmative action programs.* Each sponsor required under § 30.4 to develop and maintain an affirmative action program must retain both the written AAP and documentation of its outreach, recruitment, and retention efforts required by § 30.8, including all data and analyses made pursuant to the requirements of this part.

(d) *Maintenance of records.* The records required by this part and any other information relevant to compliance with these regulations must be maintained for 3 years from the date of the making of the record or the personnel action involved, whichever occurs later, and must be made available upon request to the Registration Agency or other authorized representative in such form as the Registration Agency may determine is necessary to enable it to ascertain whether the sponsor has complied or is complying with this part. Failure to preserve complete and accurate records as required by paragraphs (a), (b), and (c) of this section constitutes noncompliance with this part.

(e) *Confidentiality and use of medical information.* (1) Any information obtained pursuant to this part regarding the medical condition or history of an applicant or apprentice must be collected and maintained on separate forms and in separate medical files and treated as a confidential medical record, except that:

(i) Supervisors and managers may be informed regarding necessary restrictions on the work or duties of the applicant or apprentice and necessary accommodations;

(ii) First aid and safety personnel may be informed, when appropriate, if the disability might require emergency treatment; and

(iii) Government officials engaged in enforcing this part, the laws administered by OFCCP, or the ADA, must be provided relevant information on request.

(2) Information obtained under this part regarding the medical condition or history of any applicant or apprentice may not be used for any purpose inconsistent with this part.

(f) *Access to records.* Each sponsor must permit access during normal business hours to its places of business for the purpose of conducting on-site EEO compliance reviews and complaint investigations and inspecting and copying such books, accounts, and records, including electronic records, and any other material the Registration Agency deems relevant to the matter under investigation and pertinent to compliance with this part. The sponsor must also provide the Registration Agency access to these materials, including electronic records, off-site for purposes of conducting EEO compliance reviews and complaint investigations. Upon request, the sponsor must provide the Registration Agency information about all format(s), including specific electronic formats, in which its records and other information are available. Information obtained in this manner will be used only in connection with the administration of this part or other applicable EEO laws.

§ 30.13 Equal employment opportunity compliance reviews.

(a) *Conduct of compliance reviews.* The Registration Agency will regularly conduct EEO compliance reviews to determine if the sponsor maintains compliance with this part, and will also conduct EEO compliance reviews when circumstances so warrant. An EEO compliance review may consist of, but is not limited to, comprehensive analyses and evaluations of each aspect of the apprenticeship program through off-site reviews, such as desk audits of records submitted to the Registration Agency, and on-site reviews conducted at the sponsor's establishment that may involve examination of records required under this part; inspection and copying of documents related to recordkeeping requirements of this part; and interviews with employees, apprentices, journeyworkers, supervisors, managers, and hiring officials.

(b) *Notification of compliance review findings.* Within 45 business days of completing an EEO compliance review, the Registration Agency must present a written Notice of Compliance Review Findings to the sponsor's contact person through registered or certified mail, with return receipt requested. If the compliance review indicates a failure to comply with this part, the registration agency will so inform the sponsor in the Notice and will set forth in the Notice the following:

(1) The deficiency(ies) identified;

(2) How to remedy the deficiency(ies);

(3) The timeframe within which the deficiency(ies) must be corrected; and

(4) Enforcement actions may be undertaken if compliance is not achieved within the required timeframe.

(c) *Compliance.* When a sponsor receives a Notice of Compliance Review Findings that indicates a failure to comply with this part, the sponsor must, within 30 business days of notification, implement a compliance action plan and notify the Registration Agency of that plan. The compliance action plan must include, but is not limited to, the following provisions:

(1) A specific commitment, in writing, to correct or remediate identified deficiency(ies) and area(s) of noncompliance;

(2) The precise actions to be taken for each deficiency identified;

(3) The time period within which the cited deficiency(ies) will be remedied and any corrective program changes implemented; and

(4) The name of the individual(s) responsible for correcting each deficiency identified.

Upon the Registration Agency's approval of the compliance action plan, the sponsor may be considered in compliance with this part provided that the compliance action plan is implemented.

(d) *Enforcement actions.* Any sponsor that fails to implement its compliance action plan within the specified timeframes may be subject to an enforcement action under § 30.15.

§ 30.14 Complaints.

(a) *Requirements for individuals filing complaints*—(1) *Who may file.* Any individual who believes that he or she has been or is being discriminated against on the basis of race, color, religion, national origin, sex, sexual orientation, age (40 or older), genetic information, or disability with regard to apprenticeship may, personally or through an authorized representative, file a written complaint with the Registration Agency with whom the apprenticeship program is registered.

(2) *Time period for filing a complaint.* Generally, a complaint must be filed within 180 days of the alleged discrimination or specified failure to follow the equal opportunity standards. However, for good cause shown, the Registration Agency may extend the filing time. The time period for filing is for the administrative convenience of the Registration Agency and does not create a defense for the respondent.

(3) *Contents of the complaint.* Each complaint must be made in writing and must contain the following information:

(i) The complainant's name, address and telephone number, or other means for contacting the complainant;

(ii) The identity of the respondent (the individual or entity that the complainant alleges is responsible for the discrimination);

(iii) A short description of the events that the complainant believes were discriminatory, including but not limited to when the events took place, what occurred, and why complainant believes the actions were discriminatory (for example, because of his or her race, color, religion, sex, sexual orientation, national origin, age (40 or older), genetic information, or disability).

(iv) The complainant's signature or the signature of the complainant's authorized representative.

(b) *Requirements of sponsors.* Sponsors must provide written notice to all applicants for apprenticeship and all apprentices of their right to file a discrimination complaint and the procedures for doing so. The notice must include the address, phone number, and other contact information for the Registration Agency that will receive and investigate complaints filed under this part. The notice must be provided in the application for apprenticeship and must also be displayed in a prominent, publicly available location where all apprentices will see the notice. The notice must contain the following specific wording:

Your Right to Equal Opportunity

It is against the law for a sponsor of an apprenticeship program registered for Federal purposes to discriminate against an apprenticeship applicant or apprentice based on race, color, religion, national origin, sex, sexual orientation, age (40 years or older), genetic information, or disability. The sponsor must ensure equal opportunity with regard to all terms, conditions, and privileges associated with apprenticeship. If you think that you have been subjected to discrimination, you may file a complaint within 180 days from the date of the alleged discrimination or failure to follow the equal opportunity standards with [INSERT NAME OF REGISTRATION AGENCY, ADDRESS, PHONE NUMBER, AND CONTACT NAME OF INDIVIDUAL AT THE REGISTRATION AGENCY WHO IS RESPONSIBLE FOR RECEIVING COMPLAINTS].

Each complaint filed must be made in writing and include the following information:

1. Complainant's name, address and telephone number, or other means for contacting the complainant;

2. The identity of the respondent (*i.e.* the name, address, and telephone number of the individual or entity that the complainant alleges is responsible for the discrimination);

3. A short description of the events that the complainant believes were discriminatory, including but not limited to when the events took place, what occurred, and why the complainant believes the actions were discriminatory (for example, because of his/her race, color, religion, sex, sexual orientation, national origin, age (40 or older), genetic information, or disability);

4. The complainant's signature or the signature of the complainant's authorized representative.

(c) *Requirements of the Registration Agency.*—(1) *Conduct investigations.* The investigation of a complaint filed under this part will be made by the Registration Agency. In conducting complaint investigations, the Registration Agency must:

(i) Within 10 business days of receiving the complaint, provide written notice to the complainant acknowledging receipt of the complaint;

(ii) Contact the complainant within 10 business days, if the complaint form is incomplete, to obtain full information necessary to initiate an investigation.

(iii) Initiate an investigation within 15 business days of receiving a complete complaint;

(iv) Complete a thorough investigation of the allegations of the complaint within 30 business days of initiating the investigation and develop a complete case record that must contain, but is not limited to, the name, address, and telephone number of each person interviewed, the interview statements, copies, transcripts, or summaries (where appropriate) of pertinent documents, and a narrative report of the investigation with references to exhibits and other evidence which relate to the alleged violations; and

(v) Within 15 business days of completing the investigation, provide written notification of the Registration Agency's findings to both the respondent and the complainant.

(2) *Seek compliance.* Where a report of findings from a complaint investigation indicates a violation of the nondiscrimination requirements of this part, the Registration Agency must resolve the matter quickly and informally whenever possible. Where a complaint of discrimination cannot be resolved informally to the satisfaction of the complainant within 75 business days of its filing, the Registration Agency must refer the complaint to other Federal, State or local EEO agencies, as appropriate.

(3) *Referrals to other EEO agencies.* The Registration Agency, at its discretion, may choose to refer a complaint immediately upon its receipt or any time thereafter to:

(i) The EEOC;

(ii) The United States Attorney General;

(iii) The Department's OFCCP; or

(iv) For an SAA, to its Fair Employment Practices Agency.

(4) An SAA may adopt a complaint review procedure differing in detail

from that given in this section provided it is submitted for review to and receives approval by the Administrator.

§ 30.15 Enforcement actions.

Where the Registration Agency, as a result of a compliance review, complaint investigation, or other reason, determines that the sponsor is not operating its apprenticeship program in accordance with this part, the Registration Agency must notify the sponsor in writing of the specific violation(s) identified and may:

(a) Offer the sponsor technical assistance to promote compliance with this part.

(b) Suspend the sponsor's right to register new apprentices if the sponsor fails to implement a compliance action plan to correct the specific violation(s) identified within 30 business days from the date the sponsor is so notified of the violation(s).

(c) If the sponsor has not implemented a compliance action plan within 30 business days of notification of suspension, institute proceedings to deregister the program in accordance with the deregistration proceedings set forth in part 29 of this title.

(d) *Take any other action authorized by law.* These other actions may include, but are not limited to,

(1) Referral to the EEOC;

(2) Referral to an appropriate State fair employment practice agency; or

(3) Referral to the Department's OFCCP.

§ 30.16 Reinstatement of program registration.

An apprenticeship program that has been deregistered pursuant to this part may be reinstated by the Registration Agency upon presentation of adequate evidence that the apprenticeship program is operating in accordance with this part.

§ 30.17 Intimidation and retaliation prohibited.

(a) A sponsor and its employees must not intimidate, threaten, coerce, retaliate, or discriminate against any individual because the individual has:

(1) Filed a complaint alleging a violation of this part;

(2) Opposed a practice prohibited by the provisions of this part or any other Federal or State equal opportunity law;

(3) Furnished information to, or assisted or participated in any manner, in any investigation, compliance review, proceeding, or hearing under this part or any Federal or State equal opportunity law; or

(4) Otherwise exercised any rights and privileges under the provisions of this part.

(b) Any sponsor that engages in such intimidation or retaliation or fails to take appropriate steps to prevent such activity will be subject to enforcement action under § 30.15.

§ 30.18 State apprenticeship agencies.

(a) *State Plan.* (1) Within 1 year of the effective date of this part, with no exceptions of this deadline permitted, an SAA that seeks to obtain or maintain recognition under § 29.13 of this title must submit to OA a State EEO plan that:

(i) Includes the State apprenticeship law that corresponds to the requirements of this part; and

(ii) Requires all apprenticeship programs registered with the State for Federal purposes to comply with the requirements of the State's EEO plan within 180 days from the date that OA provides written approval of the State EEO plan submitted under paragraph (1) of this section.

(2) Upon receipt of the State's EEO plan, OA will review the plan to determine if the plan conforms to this part. OA will:

(i) Grant the SAA continued recognition during this review period;

(ii) Provide technical assistance to facilitate conformity, and provide written notification of the areas of nonconformity, if any; and

(iii) Upon successful completion of the review process, notify the SAA of OA's determination that the State's EEO plan conforms to this part.

(3) If the State does not submit a revised State EEO plan that addresses identified non-conformities within 90 days from date that OA provides the SAA with written notification of the areas of nonconformity, OA will begin the process set forth in § 29.14 of this title to rescind recognition of the SAA.

(4) An SAA that seeks to obtain or maintain recognition must obtain the Administrator's written concurrence in any proposed State EEO plan, as well as any subsequent modification to that plan, as provided in § 29.13(b)(9) of this title.

(b) *Recordkeeping requirements.* A recognized SAA must keep all records pertaining to program compliance reviews, complaint investigations, and any other records pertinent to a determination of compliance with this part. These records must be maintained for three years from the date of their creation.

(c) *Retention of authority.* As provided in § 29.13 of this title, OA retains the full authority to:

(1) Conduct compliance reviews of all registered apprenticeship programs;

(2) Conduct complaint investigations of any program sponsor to determine whether an apprenticeship program registered for Federal purposes is operating in accordance with this part;

(3) Deregister for Federal purposes an apprenticeship program registered with a recognized SAA as provided in §§ 29.8(b) and 29.10 of this title; and

(4) Refer any matter pertaining to § 30.18(c)(1) or (2) to the following:

(i) The EEOC or the U.S. Attorney General with a recommendation for the institution of an enforcement action under title VII of the Civil Rights Act of 1964, as amended; the ADEA; GINA, or title I of the ADA;

(ii) The Department's OFCCP with a recommendation for the institution of agency action under Executive Order 11246; or section 503 of the Rehabilitation Act of 1973, as amended; or

(iii) The U.S. Attorney General for other action as authorized by law.

(d) *Derecognition.* A recognized SAA that fails to comply with the requirements of this section will be subject to derecognition proceedings, as provided in § 29.14 of this title.

§ 30.19 Exemptions.

Requests for exemption from these regulations, or any part thereof, must be made in writing to the Registration Agency and must contain a statement of reasons supporting the request. Exemptions may be granted for good cause by the Registration Agency. State Apprenticeship Agencies must receive approval to grant an exemption from the Administrator, prior to granting an exemption from these regulations.

§ 30.20 Effective date.

(a) *Effective date for specified requirements in all currently registered programs.* Within 180 days of [effective date of the final rule], each sponsor of an apprenticeship program currently registered with a Registration Agency as of [effective date of the final rule] must:

(1) Amend its Standards of Apprenticeship to include the equal opportunity pledge prescribed by § 30.3(c);

(2) Comply with the non-discrimination requirements prescribed by § 30.3(a).

(b) *Effective date for specified requirements in programs registered with an SAA.* Sponsors of programs registered with an SAA must adopt an affirmative action program as set forth in § 30.4 that complies with the requirements of this part and have the written plan approved by its SAA. For programs registered with an SAA as of [effective date of the final rule], these actions must be completed within 180 days from the date that OA provides

written approval of a State's EEO plan, as provided under § 30.18(a). For programs registered with an SAA after [effective date of the final rule], these actions must be completed within 180 days from the date OA provides written approval of a State's EEO plan or, if OA has already approved the State's EEO plan, within one year after registration.

(c) *Effective date for specified requirements in programs registered with OA.* Sponsors of programs registered with the Office of Apprenticeship must adopt an affirmative action program as set forth in § 30.4 that complies with the requirements of this part and have the written plan approved by OA. For programs registered as of the [effective date of the final rule], these actions must be completed within one year after [effective date of the final rule]. For programs registered after [effective date of the final rule], these actions must be completed within one year after registration.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 413

Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS–1628–F]

RIN 0938–AS48

Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This rule updates and makes revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2016. This rule is necessary to ensure that ESRD facilities receive accurate Medicare payment amounts for furnishing outpatient maintenance dialysis treatments during calendar year 2016. This rule will also set forth requirements for the ESRD Quality Incentive Program (QIP), including for PYs 2017 through 2019.

DATES: *Effective Date:* These regulations are effective on January 1, 2016.

FOR FURTHER INFORMATION CONTACT: CMS ESRD *PAYMENT@cms.hhs.gov,* for issues related to the ESRD PPS payment provisions. Heidi Oumarou, (410) 786–7342, for issues related to the ESRD PPS Market Basket Update. Tamyra Garcia, (410) 786–0856, for issues related to the ESRD QIP.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/.*

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR).

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

ABLE The Achieving a Better Life Experience Act of 2014
AHRQ Agency for Healthcare Research and Quality
AMCC Automated Multi-Channel Chemistry
ANOVA Analysis of Variance
ARM Adjusted Ranking Metric
ASP Average Sales Price
ATRA The American Taxpayer Relief Act of 2012
BCMA Basic Case-Mix Adjustment
BEA Bureau of Economic Analysis
BLS Bureau of Labor Statistics
BMI Body Mass Index
BSA Body Surface Area
BSI Bloodstream Infection
CB Consolidated Billing
CBSA Core based statistical area
CCN CMS Certification Number
CDC Centers for Disease Control and Prevention
CKD Chronic Kidney Disease
CLABSI Central Line Access Bloodstream Infections
CFR Code of Federal Regulations
CIP Core Indicators Project
CMS Centers for Medicare & Medicaid Services
CPM Clinical Performance Measure
CPT Current Procedural Terminology
CROWNWeb Consolidated Renal Operations in a Web-Enabled Network
CY Calendar Year
DFC Dialysis Facility Compare
DFR Dialysis Facility Report
ESA Erythropoiesis stimulating agent
ESRD End-Stage Renal Disease
ESRDB End-Stage Renal Disease bundled
ESRD PPS End-Stage Renal Disease Prospective Payment System
ESRD QIP End-Stage Renal Disease Quality Incentive Program
FDA Food and Drug Administration
HCP Healthcare Personnel
HD Hemodialysis
HHD Home Hemodialysis
HAIs Healthcare-Acquired Infections
HCPCS Healthcare Common Procedure Coding System
HCFA Health Care Financing Administration
HHS Department of Health and Human Services
ICD International Classification of Diseases
ICD–9–CM International Classification of Disease, 9th Revision, Clinical Modification
ICD–10–CM International Classification of Disease, 10th Revision, Clinical Modification
ICH CAHPS In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
IGI IHS Global Insight
IIC Inflation-indexed charge
IPPS Inpatient Prospective Payment System
IUR Inter-unit reliability
KDIGO Kidney Disease: Improving Global Outcomes
KDOQI Kidney Disease Outcome Quality Initiative
Kt/V A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
LDO Large Dialysis Organization
MAC Medicare Administrative Contractor
MAP Medicare Allowable Payment
MCP Monthly Capitation Payment
MDO Medium Dialysis Organization
MFP Multifactor Productivity
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003
MMEA Medicare and Medicaid Extenders Act of 2010 Pub. L. 111–309
MSA Metropolitan statistical areas
NAMES National Association of Medical Equipment Suppliers
NHSN National Healthcare Safety Network
NQF National Quality Forum
NQS National Quality Strategy
NHSN National Healthcare Safety Network
NQF National Quality Forum
NQS National Quality Strategy
OBRA Omnibus Budget Reconciliation Act
OMB Office of Management and Budget
PAMA Protecting Access to Medicare Act of 2014
PC Product category
PD Peritoneal Dialysis
PEN Parenteral and Enteral nutrition
PFS Physician Fee Schedule
PPI Producer Price Index
PPS Prospective Payment System
PSR Performance Score Report
PY Payment Year
QIP Quality Incentive Program
RCE Reasonable Compensation Equivalent
REMIS Renal Management Information System
RFA Regulatory Flexibility Act
SBA Small Business Administration
SFA Small Facility Adjuster
SIMS Standard Information Management System
SRR Standardized Readmission Ratio
SSA Social Security Administration
STrR Standardized Transfusion Ratio
The Act Social Security Act
The Affordable Care Act The Patient Protection and Affordable Care Act
The Secretary Secretary of the Department of Health and Human Services
TPS Total Performance Score
URR Urea reduction ratio
VAT Vascular Access Type
VBP Value Based Purchasing

I. Executive Summary

A. Purpose

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted, bundled prospective payment system for renal dialysis services furnished by ESRD facilities.

This final rule will update and revise the ESRD PPS for calendar year (CY) 2016. Section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Public Law 110–275), and section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act Public Law 111–148), established that beginning CY 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2011, to reduce the single payment amount to reflect the Secretary's estimate of the utilization of ESRD-related drugs and biologicals. We finalized the amount of the drug utilization adjustment pursuant to this section in the CY 2014 ESRD PPS final rule with a 3- to 4-year transition (78 FR 72161 through 72170). Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS before January 1, 2016. Section 632(c) of ATRA requires the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Congress enacted the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93). Section 217 of PAMA includes several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amend sections 1881(b)(14)(F) and (I) of the Act. We interpreted the amendments to sections 1881(b)(14)(F) and (I) as replacing the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule with specific provisions that dictate the market basket update for CY 2015 (0.0 percent) and how it will be reduced in CYs 2016 through 2018. Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only drugs and biologicals used for the treatment of ESRD under the ESRD PPS prior to January 1, 2024. Section 217(c) of PAMA provides that, as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

On December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

This rule also finalizes to set forth requirements for the ESRD QIP, including for payment years (PYs) 2017, 2018, and 2019. The program is authorized under section 1881(h) of the Social Security Act (the Act). The ESRD QIP is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by CMS.

B. Summary of the Major Provisions

1. ESRD PPS

- *ESRD PPS refinement:* In accordance with section 632(c) of ATRA, we analyzed the case-mix payment adjustments under the ESRD PPS using more recent data. For this final rule, we have revised the adjustments by changing the adjustment payment amounts based on our updated regression analysis using CYs 2012 and 2013 ESRD claims and cost report data. In addition, we will remove two comorbidity category payment adjustments (bacterial pneumonia and monoclonal gammopathy). Because we conducted an updated regression analysis to enable us to analyze and revise the case-mix payment adjustments, this final rule also revises the low-volume payment adjustment (LVPA) and implements a new rural adjustment based on that regression analysis. We are finalizing new patient and facility-level adjustment factors. This final rule also revises the geographic proximity eligibility criterion for the LVPA and removes grandfathering from the criteria for the adjustment.
- *Drug designation process:* In accordance with section 217(c) of PAMA, this final rule will implement a drug designation process for: (1) Determining when a product is no longer an oral-only drug and (2) including new injectable and intravenous renal dialysis service drugs and biologicals into the bundled payment under the ESRD PPS.
- *Update to the ESRD PPS base rate for CY 2016:* The final CY 2016 ESRD PPS base rate is $230.39. This amount reflects a reduced market basket increase as required by section 1881(b)(14)(F)(i)(I) (0.15 percent), application of the wage index budget-neutrality adjustment factor (1.000495), and a refinement budget-neutrality adjustment factor (0.960319). The final CY 2016 ESRD PPS base rate is $230.39 ($239.43 x 1.000495 x 1.0015 x 0.960319 = $230.39).
- *Annual update to the wage index and wage index floor:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2016, we will complete our 2-year transition to both the updated CBSA delineations and the labor-related share to which the wage index is applied (50.673 percent). In addition, we computed a wage index budget-neutrality adjustment factor of 1.000495 which is applied to the ESRD PPS base rate. We are finalizing the continuation of the application of the current wage index floor (0.4000) to areas with wage index values below the floor.
- *Update to the outlier policy:* We are updating the outlier policy using the most current data. Specifically, we are updating the outlier services fixed dollar loss amounts for adult and pediatric patients and Medicare Allowable Payments (MAPs) for adult patients for CY 2016 using 2014 claims data. Based on the use of more current data, the fixed-dollar loss amount for pediatric beneficiaries increases from $54.35 to $62.19 and the MAP amount decreases from $43.57 to $39.20, as compared to CY 2015 values. For adult beneficiaries, the fixed-dollar loss amount increases from $86.19 to $86.97 and the MAP amount decreases from $51.29 to $50.81. The 1.0 percent target for outlier payments was not achieved in CY 2014 (0.8 percent rather than 1.0 percent). We believe using CY 2014 claims data to update the outlier MAP and fixed dollar loss amounts for CY 2016 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1.0 percent outlier percentage.

2. ESRD QIP

This rule sets forth requirements for the ESRD QIP, including for payment years (PYs) 2017, 2018 and 2019.

- *PY 2019 Measure Set:* For PY 2019 and future payment years, we are removing four clinical measures—(1) Hemodialysis Adequacy: Minimum delivered hemodialysis dose; (2) Peritoneal Dialysis Adequacy: Delivered dose above minimum; (3) Pediatric Hemodialysis Adequacy: Minimum spKt/V; and (4) Pediatric Peritoneal Dialysis Adequacy—because a more broadly applicable measure for the topic has become available. We are replacing these measures with a single comprehensive Dialysis Adequacy clinical measure.
- *Reinstating the In-Center Hemodialysis Consumer Assessment of Healthcare Providers (ICH CAHPS) Attestation:* Beginning with PY 2017, we are reinstating the ICH CAHPS attestation in Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) previously adopted in the CY 2014 ESRD PPS final rule (78 FR 72220 through 72222) using the eligibility criteria finalized in the CY 2015 ESRD PPS final rule (79 FR 66169). This will allow facilities to attest in CROWNWeb that they did not treat enough eligible patients during the eligibility period to receive a score on the ICH CAHPS measure and thereby avoid receiving a score for this measure.
- *Revising the Small Facility Adjuster:* Beginning with the PY 2017 ESRD QIP, we are revising the Small Facility Adjuster (SFA) such that it does not rely upon a pooled within-facility standard error. The revised SFA preserves the intent of the adjuster to include as many facilities in the ESRD QIP as possible while ensuring that the measure scores are reliable.

C. Summary of Costs and Benefits

In section VI of this final rule, we set forth a detailed analysis of the impacts that the changes will have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact chart in section VI of this final rule displays the estimated change in payments to ESRD facilities in CY 2016 compared to estimated payments in CY 2015. The overall impact of the CY 2016 changes is projected to be a 0.2 percent increase in payments. Hospital-based ESRD facilities and freestanding facilities both have an estimated 0.2 percent increase in payments.

We estimate that the aggregate ESRD PPS expenditures will increase by approximately $10 million from CY 2015 to CY 2016 which reflects the payment rate update. As a result of the projected 0.2 percent overall payment increase, we estimate that there will be an increase in beneficiary co-insurance payments of 0.2 percent in CY 2016, which translates to approximately $0 million due to rounding.

2. Impacts of the Final ESRD QIP

The overall economic impact of the ESRD QIP is an estimated $11.8 million in PY 2018 and $15.5 million in PY 2019. In PY 2018, we expect the costs associated with the collection of information requirements for the data validation studies to be approximately $21 thousand for all ESRD facilities, totaling an overall impact of approximately $11.8 million as a result of the PY 2018 ESRD QIP.[1] In PY 2019, we expect the overall impact to be approximately $15.5 million.

The ESRD QIP will continue to incentivize facilities to provide high-quality care to beneficiaries.

II. Calendar Year (CY) 2016 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background on the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the end-stage renal disease (ESRD) prospective payment system (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities based on the requirements of section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA requires the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Congress enacted the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L.113–93). Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CYs 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, we must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, section 212 of PAMA provided that the Secretary may not

[1] We note that the aggregate impact of the PY 2018 ESRD QIP was included in the CY 2015 ESRD PPS final rule (79 FR 66256 through 66258). The previously finalized aggregate impact of $11.8 million reflects the PY 2018 estimated payment reductions and the collection of information requirements for the NHSN Healthcare Personnel Influenza Vaccination reporting measure.

adopt the International Classification of Disease 10th Revision, Clinical Modification (ICD–10–CM) code sets prior to October 1, 2015. HHS published a final rule on August 4, 2014 that adopted October 1, 2015 as the new ICD–10–CM compliance date, and required the use of International Classification of Disease, 9th Revision, Clinical Modification (ICD–9–CM) through September 30, 2015 (79 FR 45128).

On December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

1. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definitions of renal dialysis services at 42 CFR 413.171 and other payment policies are included in regulations at subpart H of 42 CFR part 413. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and account for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area (BSA), low body mass index (BMI), onset of dialysis, six co-morbidity categories, and pediatric patient-level adjusters consisting of two age categories and dialysis modalities (42 CFR 413.235(a) and(b)).

In addition, the ESRD PPS provides for two facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (42 CFR 413.232). The second adjustment reflects differences in area wage levels developed from Core Based Statistical Areas (CBSAs) (42 CFR 413.231).

The ESRD PPS allows for a training add-on payment adjustment for home dialysis modalities (42 CFR 413.235(c)). Lastly, the ESRD PPS provides additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable (42 CFR 413.237).

2. Updates to the ESRD PPS

Updates and policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS we have published annual rules to make routine updates, policy changes, and clarifications.

On November 6, 2014, we published in the **Federal Register** a final rule (79 FR 66120 through 66265) titled, ''End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies'' (hereinafter referred to as the CY 2015 ESRD PPS final rule). In that final rule, we made a number of routine updates to the ESRD PPS for CY 2015, completed a rebasing and revision of the ESRD bundled market basket, implemented a 2-year of transition for the revised labor-related share and a 2-year transition of the new Core-Based Statistical Area (CBSA) delineations, and made policy changes and clarifications. For a summary of the provisions in that final rule, we refer readers to the CY 2016 ESRD PPS proposed rule at 80 FR 37813 (July 1, 2015).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2016 ESRD PPS Proposed Rule

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program'' (80 FR 37807 through 37860), (hereinafter referred to as the CY 2016 ESRD PPS proposed rule), was published in the **Federal Register** on July 1, 2015, with a comment period that ended on August 25, 2015. In that proposed rule, for the ESRD PPS, we proposed to (1) make a number of routine updates for CY 2016, (2) implement the statutory provisions set forth in ATRA and PAMA, and (3) clarified policies for reporting renal dialysis services on the ESRD facility claim. We received 233 public comments on our proposals, including comments from: ESRD facilities, national renal groups, nephrologists and patient organizations, patients and care partners, manufacturers, health care systems, and nurses. Of those comments, 67 were related to the provisions in the proposed rule. As part of the comments received, there was a write-in campaign from 200 individuals that addressed home dialysis training. We also received comments that pertained to topics that were outside of the scope of this rule, for example, network fees and Part D payment determinations.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2016 ESRD PPS. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

1. Analysis and Revision of the Payment Adjustments Under the ESRD PPS

a. Development and Implementation of the ESRD PPS Payment Adjustments

Section 153(b) of MIPPA amended section 1881(b) of the Act to require the Secretary to implement the ESRD PPS effective January 1, 2011. Section 1881(b)(14)(D)(i) requires the ESRD PPS to include a payment adjustment based on case-mix that may take into account patient weight, body mass index (BMI), comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors. Section 1881(b)(14)(D)(ii) through (iv) provide that the ESRD PPS must also include an outlier payment adjustment and a low-volume payment adjustment, and may include such other payment adjustments as the Secretary determines appropriate.

In response to the MIPPA amendments to section 1881(b) requiring the new bundled ESRD PPS, we published the proposed ESRD PPS design and implementation strategy in the **Federal Register** on September 29, 2009 (74 FR 49922).

In that rule (75 FR 49033) we noted that section 623(f)(1) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, required the Secretary to submit to the Congress a report detailing the elements and features for the design and the implementation of the ESRD PPS. To meet this mandate we worked with the University of Michigan—Kidney Epidemiology and Cost Center (UM–KECC) in developing the ESRD PPS and used their report that provided their findings and recommendations submitted to CMS in February 2008, titled, *End-Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle* (herein referred to as Technical Report) as the basis for the Secretary's

February 2008 Report to Congress, *A Design for a Bundled End Stage Renal Disease Prospective Payment System.* These reports can be found on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/educational_resources.html.*

We received over 1400 comments from dialysis facilities, Medicare beneficiaries, physician groups, and other stakeholders in response to the proposed rule. In consideration of these comments, we finalized the case-mix and facility-level adjustments for the ESRD PPS in the CY 2011 ESRD PPS final rule (75 FR 49030). For a complete discussion of public comments and the finalized payment policies for the ESRD PPS, we refer the reader to the CY 2011 ESRD PPS final rule (75 FR 49030 through 49214).

b. Regression Model Used To Develop Payment Adjustment Factors

i. Regression Analysis

In the CY 2011 ESRD PPS final rule (75 FR 49083), we discuss the two-equation methodology used to develop the adjustment factors that would be applied to the base rate to calculate each patient's case-mix adjusted payment per treatment. The two-equation approach used to develop the ESRD PPS included a facility-based regression model for services historically paid for under the composite rate as indicated in ESRD facility cost reports, and a patient-month-level regression model for services historically billed separately. The models used for the 2011 final rule were based on 3 years of data (CYs 2006 through 2008).

Section 632(c) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 11–240) requires the Secretary, by no later than January 1, 2016, to conduct an analysis of the case-mix payment adjustments being used under section 1881(b)(14)(D)(i) of the Act and to make appropriate revisions to such case-mix payment adjustments. In the proposed rule (80 FR 37814) we explained that while section 632(c) of ATRA only requires us to analyze and make appropriate revisions to the case-mix payment adjustments, we performed a regression analysis that updated all of the payment multipliers including the low-volume payment adjustment. Also, as discussed in more detail in section II B.d.iii of this final rule, we analyzed rural areas as a payment variable in our regression analysis and proposed to implement a new adjustment for this facility characteristic.

For purposes of analyzing and proposing revisions to the payment adjusters included in the proposed rule, we updated the two-equation methodology using CY 2012 and 2013 Medicare cost report and claims data. Data from CYs 2012 and 2013 is the most recently available information that we had to implement the refinement of the ESRD PPS in CY 2016 as required by section 632(c) of ATRA. Generally, we would have used 3 years of data as we did when we established the existing case-mix adjusters. However, 2011 was the first year under the new bundled payment system. The revised FDA *black box* warning for erythropoiesis-stimulating agents (ESAs) was also issued during 2011. These two factors may have been associated with changing practice patterns during 2011. Updating the regression analysis using the most recent claims and cost report data allows the case-mix adjustment model to reflect practice patterns that have prevailed under the incentives of the expanded bundled payment system. Therefore, we used CYs 2012 and 2013 data for the refinements to the case-mix systems.

In the proposed rule (80 FR 37817 through 37818 and 37821 through 37823, respectively), we proposed to reduce the number of comorbidity categories to which payment adjusters apply and implement an adjustment for rural facilities. Our rationale for proposing to eliminate two of the comorbidity categories for which we will make payment adjustments is discussed in section II B.1.c.i of this final rule. The measures of resource use, specified as the dependent variables for developing the payment model in each of the two equations are explained below.

ii. Dependent Variables

(1) Average Cost per Treatment for Composite Rate Services

For purposes of the proposed rule, we measured resource use, for example, time on a dialysis machine for the maintenance dialysis services included in the bundle of composite rate services, using only ESRD facility data obtained from the Medicare cost reports for freestanding ESRD facilities and hospital-based ESRD facilities. We used facility level data because no data are available at the patient-level that reflect variation in resources costs for providing composite rate services. In addition, cost report data is the only data that we have available that reports facility costs and is certified by the facility as being accurate. The average composite rate cost per treatment for each ESRD facility was calculated by dividing the total reported allowable costs for composite rate services for cost reporting periods ending in CYs 2012 and 2013 (Worksheet B, column 11A, lines 8–17 on CMS–265–11; Worksheet I–2, column 11, lines 2–11 on CMS–2552–10) by the total number of dialysis treatments (Worksheet C, column 1, lines 8–17 on CMS 265–11; Worksheet I–4, column 1, lines 1–10 on CMS–2552–10). CAPD and CCPD patient weeks were multiplied by 3 to obtain the number of HD-equivalent treatments. We note that our computation of the total composite rate costs included in this per treatment calculation includes costs incurred for training expenses, as well as all costs incurred by ESRD facilities for home dialysis patients.

The resulting cost per treatment was adjusted to eliminate the effects of varying wage levels among the areas in which ESRD facilities are located using the ESRD PPS CY 2015 wage indices and the new CBSA delineations which were discussed in the CY 2015 ESRD PPS final rule, as well as the estimated labor-related share of costs from the composite rate market basket. This was done so that the relationship of the studied variables on dialysis facility costs would not be confounded by differences in wage levels.

The proportion of composite rate costs determined to be labor-related (53.711 percent of each ESRD facility's composite rate cost per treatment) was divided by the ESRD wage index to control for area wage differences. No floor or ceiling was imposed on the wage index values used to deflate the composite rate costs per treatment in order to give the full effect to the removal of actual differences in area wage levels from the data. We applied a natural log transformation to the wage-deflated composite rate costs per treatment to better satisfy the statistical assumptions of the regression model, and to maintain consistency with existing case-mix adjustment methods, in which a multiplicative payment adjuster is applied for each case-mix variable.

As with other health care cost data, the cost distribution for resource/dialyzing composite rate services was skewed (due to a relatively small fraction of observations accounting for a disproportionate fraction of costs). Cost per treatment values which were determined to be unusually high or low in accordance with predetermined statistical criteria were excluded from further analysis. (For an explanation of the statistical outer fence methodology used to identify unusually high and low

composite rate costs per treatment, see pages 45 through 48 of the Secretary's February 2008 Report to Congress, *A Design for a Bundled End Stage Renal Disease Prospective Payment System.* This document is available on the CMS Web site at the following link: *http://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDGeneralInformation/downloads/ESRDReportToCongress.pdf.*

(2) Average Medicare Allowable Payment (MAP) for Previously Separately Billable Services

For purposes of the proposed rule, resource use for separately billable items and services used for the treatment of ESRD was measured at the patient-level using the utilization data on the Medicare claims by quarter for CYs 2012 and 2013 and average sales prices plus 6 percent of the drug or biological, if applicable, for each quarter. This time period corresponded to the most recent 2 years of Medicare cost report data that were available to measure resource use for composite rate services, such as time dialyzing. Measures of resource use included the following separately billable services: injectable drugs billed by ESRD facilities, including ESAs; laboratory services provided to ESRD patients, billed by freestanding laboratory suppliers and ordered by physicians who receive monthly capitation payments for treating ESRD patients, or billed by ESRD facilities; and other services billed by ESRD facilities.

iii. Independent Variables

Two types of independent or predictor variables were included in the composite rate and separately billable regression equations—case-mix payment variables and control variables. Case-mix payment variables were included as factors that may be used to adjust payments in either the composite rate or in the separately billable equation. Control variables, which generally represent characteristics of ESRD facilities such as size, type of ownership, facility type (whether hospital-based or freestanding), were specifically included to obtain accurate estimates of the payment impact of the potential payment variables in each equation. In the absence of using control variables in each regression equation, the relationship between the payment variables and measures of resource use may be biased because of correlations between facility and patient characteristics.

iv. Control Variables

Several control variables were included in the regression analysis. They were: (1) renal dialysis facility type (hospital-based versus freestanding facility); (2) facility size (4,000 dialysis treatments or fewer, but not eligible for the low-volume payment adjustment, 4,000 to 4,999, 5,000 to 9999, and 10,000 or more dialysis treatments); (3) type of ownership (independent, large dialysis organization, regional chain, unknown); (4) calendar year (2012 and 2013); and (5) home dialysis training treatments, in which the proportion of training treatments furnished by each dialysis facility is specified. The use of training treatments as a control was done in order to remove any confounding cost effects of training on other independent variables included in the payment model, particularly the onset of dialysis within 4-months variable.

The comments we received on the refinement regression methodology and our responses are set forth below:

Comment: We received several comments from dialysis associations and MedPAC questioning the validity and the stability of the current ESRD PPS payment model, that is, the two-equation regression analysis and the proposed refinements, pointing to concerns with the underlying data and statistical methodology. Some commenters made suggestions for future improvements. For example, commenters suggested that we use a one-equation model while others requested that we update the two-equation model, but retain certain multipliers from the 2011 payment model.

Response: We thoroughly reviewed these comments in consultation with our research team and other internal experts. We examined the outcomes of the current ESRD PPS specifically looking at access and quality of the PPS. Based on our comprehensive monitoring of health outcomes and access under the ESRD PPS, we believe the current payment model has been successful in allocating payments across facilities and patients while supporting access and quality. While we recognize there can be theoretically optimal approaches to addressing payment model design, the availability of data is often an important factor in the approach ultimately undertaken. This is true with the ESRD PPS and the use of a two-equation model that relies on both claims and cost report data, as other payment systems do under Medicare.

Section 632(c) of ATRA requires the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments. Given the incentives inherent with moving to a bundled PPS and resulting changes in facility cost structure, it is appropriate to review the payment model and consider changes to support accurate payments and continued access for Medicare beneficiaries.

Both at the time the CY 2016 ESRD PPS proposed rule was published and after consideration of the public comments, we believed and continue to believe that our two-equation regression analysis is the most appropriate methodology that uses the most recently available data to develop the most accurate patient- and facility-level payment adjustments that reflect cost variation for ESRD facilities. We note that the analytical results underlying the proposed refinements are similar to past payment analyses associated with the development and implementation of the ESRD PPS and have thus been stable over time.

For example, no variables were determined to be no longer statistically significant and overall there were minimal variations in adjustment factors that resulted from the refinement. Therefore, we believe the current model, including the proposed refinements, is reliable. The only modifications to the list of payment adjusters were the addition of a rural adjustment and the elimination of two comorbidities based on administrative burden.

Throughout the comments and responses within this section, we provide details regarding the model in response to the criticisms submitted by stakeholders to illustrate our position that this refinement was best accomplished by updating the two-equation regression analysis finalized in the CY 2011 ESRD PPS final rule. We believe that moving forward with an updated model aligns with our goals for the ESRD PPS in establishing accurate payments and safeguarding access for Medicare beneficiaries. As noted above, we modeled the ESRD PPS using methodologies that have been tested since the Basic Case-Mix Adjusted (BCMA) composite rate payment system and in using the most recently available data, we made our best estimate for predicting the payment variables that best reflect cost variation among ESRD facilities for furnishing renal dialysis services to a vulnerable population of patients. As we noted above, this refinement uses data that illustrates a fully bundled prospective payment system and reflects the practice patterns

under such environment. We believe that it would not be appropriate to both perpetuate certain payment adjusters into the future that were developed using pre-PPS data and update the other adjusters using ESRD claims data and cost reports from 2012 and 2013. By using the proposed two-equation model we will better target payments to those patient- and facility-level characteristics that are necessary for patients to receive access to quality care.

We appreciate the suggestions of the commenters for improvements in the model and will continue to examine this critical area of the Medicare program.

Comment: Commenters contended that the proposed rule did not include the entire specification of the two-equation regression analysis. The commenters requested that CMS release the data reports that support the proposed changes for both the facility- and patient-based regressions, including those for the control variables. In addition, commenters said CMS should explain the calculation of the weights used to combine factors from each regression. Several organizations commented that without data, descriptions, and explanations with regard to the proposed modifications to the ESRD PPS, it is difficult to provide a complete analysis and offer the most constructive comments possible. They explained that if this information was made available, then it would be possible for others in the community to replicate our model.

Response: As we stated above, section 632(c) of ATRA directed us to analyze and make appropriate revisions to the case-mix payment adjustments being used under section 1881(b)(14)(D)(i) of the Act. Because these adjustments were calculated using the two-equation payment model that was finalized in the CY 2011 ESRD PPS final rule, we believe it was appropriate to revise the adjustments using the same methodology. We accomplished this task through analysis of the model with updated claims and cost report data from 2012 and 2013. These comments pertain more to the initial design of the system for the 2011 implementation. Therefore, because the details of the elements and features for the design and the implementation of the ESRD PPS were made available at that time and are still available to this day, we referenced the CY 2011 ESRD PPS final rule for all the information and on the design.

As we stated above, in the CY 2011 ESRD PPS final rule (75 FR 49033) we noted that we worked with UM–KECC in developing the ESRD PPS and used their report that provided their findings and recommendations submitted to CMS in February 2008, titled, *End-Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle* (herein referred to as Technical Report) as the basis for the Secretary's February 2008 Report to Congress, *A Design for a Bundled End Stage Renal Disease Prospective Payment System.* Since both of these reports and the CY 2011 ESRD PPS preamble language for the proposed and final rules are readily available and extensively detail the methodology for the two-equation regression analysis that applies to the current model, we believe that this information when combined with the information in the proposed rule and the claims and cost reports for 2012 through 2013 would allow an accurate replication. As stated above, both reports were available on the web at the time the CY 2016 ESRD PPS proposed rule was published at the following hyperlink: *https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDGeneralInformation/downloads/ESRDReportToCongress.pdf* for the Secretary's February 2008 Report to Congress along with UM–KECC's Technical Report located at *http://www.kecc.sph.umich.edu/sites/default/files/attachments/publications/UM_KECC_ESRD_Bundle_Report.pdf.* We note that while UM–KECC's link to the Technical Report has changed since the issuance of the CY 2011 ESRD PPS final rule, their Web site provides assistance for locating the file. These reports and other resource materials regarding the ESRD PPS can be found on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/educational_resources.html.We* also note that we are developing an updated Technical Report that will reflect the CY 2016 refinements and will notify stakeholders when it is available.

Comment: MedPAC expressed concern about continuing to use a two-equation model to estimate the ESRD PPS adjustment factors. They indicated that the costs associated with separately billable services may be included in the cost centers that are used to derive the dependent variable (composite rate cost per treatment) for the facility level regression. They specifically noted that renal dialysis supplies could be double counted in this way. They noted that the dependent variable for the patient-level regression is the payment per treatment for separately billable services. MedPAC further explained that to combine facility- and patient-based estimates for a given variable, CMS weights each estimate by the proportion of cost or payment represented by the dependent variable in each regression, and then multiplies the two weighted estimates together to produce a final adjustment factor. They stated that if separately billable services are included in the dependent variable for both regressions, the weights will not distinguish the relative cost or payment addressed by each regression.

In addition, MedPAC expressed concern that multiplying factors from the facility-level and patient-level regressions may diminish the accuracy of the combined factors. MedPAC indicated that the distribution of average treatment cost across facilities is quite likely different than the distribution of payments for separately billable services across patients, and combining the two factors estimated based on unrelated distributions may not accurately reflect cost variation for the payment unit, a dialysis treatment. Another commenter similarly stated that the combination of coefficients from the two regressions into a single adjuster is problematic. This commenter noted that the weighting CMS used to calculate the adjuster values is not described, but that it would be incorrect to assume that the distributions for the two regressions are the same. MedPAC contended that if the distributions are not the same, then the accuracy of the resulting adjuster will be compromised.

MedPAC suggests that CMS develop payment adjustment factors using a one-equation methodology that accounts for variation in the cost of providing the full PPS payment bundle as a solution to the issues they have identified. They indicate that it may not be feasible to develop such a methodology for CY 2016, but expect to see such a change in a future revision.

Response: MedPAC has recognized the necessity of multi-equation models in other Medicare payment systems. Specifically, Medicare's home health PPS uses a 4-equation model in order to appropriately reflect resource use and align this use with payment. However, we understand the appeal of the one-equation model in terms of simplicity. For example, the Inpatient Prospective Payment System (IPPS) relies on patient-level cost information using facility-level charges reported on claims adjusted by a cost-to-charge ratio derived from the cost report. The ESRD PPS is not currently able to utilize a one-equation method because ESRD facilities do not report charges associated with the components of dialysis treatment costs that vary across patients, such as time on machine. In other words, patient-level claims provide line item detail on the use of the formerly separately billable (SB)

services, but do not provide any information regarding variation across patients in the use of the formerly composite rate (CR) services. In addition, we believe that capturing the resource cost for furnishing renal dialysis services is complex since Medicare has historically paid a base rate (that is, composite rate payment) to account for those costs which were never itemized on a claim but were reported through the cost report. We believe that the current ESRD PPS model captures this complexity through the analysis of data on case-mix and control variables gleaned from both cost reports and claims.

We note that in the analyses completed for the CY 2011 ESRD PPS proposed rule, we tested various one-equation approaches to estimate accurate adjusters and found that such facility-level estimates did not yield reliable and precise estimates for the relationships of uncommon patient characteristics (such as comorbidities) or uncommon treatment types (such as home dialysis training treatments) and CR costs. The one-equation model had low statistical power, that is, minimal ability to effectively explain variation in cost, especially for uncommon conditions as noted above. Adjusters for factors such as uncommon comorbidities could be reliably developed in the patient-level SB model, but not in the facility-level CR model. case-mix Ultimately, having charges or line item utilization data that vary meaningfully with resource use at the patient level would allow for the estimation of a valid, one-equation model. The only feasible one-equation option using currently available data would be at the facility level, which would make no use of available information from claims on the patient-level variation in SB costs and sacrifice the ability to derive any reliable adjustment for comorbidities, and commenters from the SDOs have supported the retention of the comorbid payment adjustments. Therefore, we believe developing a charge structure that could enable us to utilize a one-equation model may be worth exploring in the future, but for the data that currently exists, the two-equation model is valid, stable and retains its predictive value.

In summary, we appreciate the commenters' suggestions and will consider various options for a one-equation model in the future. For the reasons given above, and based on the data we currently have available to us, we believe the two-equation model is valid and is an appropriate method to revise the values of the adjusters.

We appreciate the recommendations and suggestions of the commenters and will consider soliciting ideas from our stakeholders to assist us in gathering the necessary data to consider a valid one-equation model as a valid ESRD PPS payment option in the future.

In regards to MedPAC's concerns about how the costs of separately billable services may be included in the cost centers that are used to derive the dependent variable for composite rate cost per treatment, we believe that the potential magnitude of double-counting certain costs such as dialysis supplies in both equations is minimal. We provide instructions to the ESRD facilities not to report items and services on their claims that are considered in the composite rate. Since we analyze claims data each year for rulemaking, we are aware of what ESRD facilities are reporting on claims with respect to utilization of renal dialysis services. Over the years, we have found that those costs associated with composite rate services was near zero. ESRD facilities have historically not reported supplies on their claims. We only allow two supplies to count toward the outlier payment: A4657 syringe, with or without needle, each of which covers the injection administration-supply charge (includes the cost of alcohol swab, syringe, and gloves) and A4913 miscellaneous dialysis supplies, not otherwise specified, which covers the intravenous administration-supply charge (includes the cost of intravenous solution administration set, alcohol swab, syringe, and gloves). Therefore, we only expect to see these two supplies reported on the claim because prior to the implementation of the PPS they were separately payable when they were used in the administration of intravenous drugs during dialysis and it would be appropriate for their inclusion in both models. Also, the costs associated with these items are minimal. Approximately $17,000 of supply costs were reported in 2014 claims based on the June 2015 claims file, which included approximately 4 million claims with a total Medicare payment of approximately $9 billion. Therefore, even if 100 percent of these costs were also reported as CR costs on the cost reports, the consequent double-counting would have a negligible impact on estimated cost per treatment, and will not have the effect with which MedPAC is concerned, namely, accurately distinguishing the relative cost or payment addressed by each regression.

In regards to MedPAC's and other commenters' concerns about how multiplying factors from the two equations could diminish the accuracy of the combined factors, we believe the impact of this concern is also minimal. The method of combination, weighting the CR or SB equation's multiplier by the share of total per treatment costs, is unchanged from when the ESRD PPS was first implemented in 2011. The only change is that the weight assigned to the SB equation has declined due to changes in practice patterns following the implementation of the ESRD PPS (primarily reductions in use of previously separately-billed drugs); the share of per treatment costs attributed to SB services declined from 32.1 percent in the 2011 payment model to 19.2 percent in the 2016 payment model. Therefore, the CR analysis estimates the facility-level relationship between case-mix measures aggregated across patients and average cost per treatment for composite rate services. The facility-level model has been successfully used to estimate statistically significant relationships between a number of case-mix characteristics measured at the facility level and average cost per treatment at the facility level since the BCMA composite rate payment system was implemented in 2004. As noted above, the facility-level model has not allowed us to estimate accurate payment adjustments for uncommon conditions such as the comorbidities that are included in the patient level SB model or the effects of uncommon treatment types such as home dialysis training. Therefore, we have refrained from estimating such payment adjusters from a facility-level model.

Comment: MedPAC also noted that through the various revisions of the two-equation model the reference group for the age adjustment shifted from ages 45–59 in the CY 2011 ESRD PPS proposed rule to ages 60–69 in the CY 2011 ESRD PPS final rule, and to ages 70–79 for the CY 2016 ESRD PPS proposed rule. MedPAC indicated that they would expect that the relative cost of dialysis across age categories to remain relatively stable over time and expressed concern that such shifts could indicate that the estimated factors are highly sensitive to the model's specification and that the model lacks robustness. They further stated that the two-equation approach might contribute to the shifting in reference groups through the various revisions to the model.

Response: We do not believe the change is as significant as MedPAC has expressed as there was very little variation in the age coefficients between the 2011 model and the 2016 model. Furthermore, in the 2011 model, the 70–79 age category only had costs 1.1 percent higher than the reference group

of 60–69. Historically, we have had narrowly defined age categories. In the analyses for both payment year 2011 and payment year 2016, the highest costs were observed for the youngest adult age group (ages 18–44), and there were relatively smaller differences in cost across the middle age categories. We expected some variation in the 2016 multipliers as a result of updated claims and cost report data since they were first derived in 2011. The final 2011 regression analysis used 2006, 2007 and 2008 claims and cost report information while the 2016 regression analysis used 2012 and 2013 claims and cost report information. Considering the significant changes that have occurred in the practice patterns of ESRD facilities, such as the significant reduction in the use of ESAs and other renal dialysis services, the minimal overall change in the coefficients appears to indicate that the model is stable. We believe this result confirms the ability of the two-equation methodology to appropriately recognize the costs for providing renal dialysis services in an ESRD facility. For these reasons, we do not believe the change in the age reference group over time indicates a problem with the regression model.

Comment: MedPAC expressed concern that using unaudited cost reports could pose a threat to the validity of the payment adjustment factors since historically facilities' cost reports have included costs that Medicare does not allow. They noted that PAMA funded CMS to audit a representative sample of ESRD facility cost reports beginning in 2014. They indicated that they knew the audits have not been completed at the time of this final rule but would be interested in learning if there are any differences in the payment adjustment factors that are derived from pre- versus post-audited data.

With respect to the use of hospital-based cost reports to derive the payment adjustment factors, MedPAC expressed that there is no guarantee of consistency in the methods used to allocate hospital costs to dialysis departments and to dialysis cost categories. They noted that CMS has said that expense data for hospital-based cost reports reflect the allocation of overhead over the entire institution, and that the expenses of each hospital-based component may be skewed. MedPAC further noted that for these reasons, the inclusion of hospital-based cost reports likely increases statistical noise in the two-equation regression methodology.

Response: As for the use of unaudited cost report data, we used the best available data for this refinement. We do not expect to have results from audits of ESRD cost reports required by section 217(e) of PAMA for some time. We believe this refinement is necessary because it reflects costs and practice patterns under the ESRD PPS. In addition, section 632(c) of ATRA requires us to analyze and make appropriate revisions to the case-mix payment adjustments by not later than January 1, 2016, and therefore, we cannot wait until after cost reports have been audited to revise the case-mix adjustments. After analyzing the adjustments, we believe the revisions we are adopting are appropriate and necessary to reflect the drop in the use of ESAs and other renal dialysis drugs.

With regard to the use of hospital-based cost reports, we agree that the issue of allocation of costs to the dialysis unit is unique to hospital-based cost reports. As part of the cost reporting process, hospitals can allocate costs to hospital-based dialysis facilities. There may be variation among hospitals regarding the methodology of cost allocation, with some hospitals under-allocating and others over-allocating costs to hospital-based dialysis facilities. The model does include an indicator of hospital-based status as a control variable. This will capture differences between hospital-based and freestanding facilities on average. Our preference is to include hospital-based facilities, while acknowledging concerns about the data, in order to represent the cost experience of all providers. We believe the concerns about the data would be more salient if the data were being used to set the base rate rather than being used only to determine the relative costliness of different case-mix factors. Also, we note that the freestanding cost reports were available before the hospital-based cost reports, so preliminary analyses did not include hospital-based cost reports. When the hospital-based cost reports were added, the payment multipliers did not change substantially, suggesting that the decision to include or exclude hospital-based reports will not have a significant impact. Including them reflects our preference that the data used to determine payment adjusters is as broadly reflective of the patients and facilities being paid under the ESRD PPS as possible.

Comment: MedPAC expressed concern that data from 2012 may not reflect current practice patterns particularly with the use of renal dialysis drugs and biologicals because drug use has continued to decline in recent years. MedPAC suggested that we use data from 2013 and beyond to update the payment adjusters since they believe that using only 2013 data would ensure better accuracy of the payment adjusters.

Response: The 2011 model was based on 3 years of data and we wanted to maintain that approach for the refinement. However, for the 2016 payment year, we did not use 1 year (2011) of data due to concerns similar to those raised by MedPAC. However eliminating an additional year, 2012, of data would decrease the accuracy of the CR model due to the decrease in the amount of data available to estimate the statistical relationships between case-mix and cost. Specifically, the sample size would be halved. For this reason, we did not adopt this suggestion and retained CY 2012 data in the regression analyses.

As we stated above, we brought the commenter's criticisms to our experts in order to ensure commenter's concerns were addressed. Their opinion was that dropping 2012 for the SB model only would still result in an accurate SB model due to the large sample size since this is a patient-level model, but then would be inconsistent with the timing of the data used in the CR model. As a result of these discussions, we continue to believe that the refinement for CY 2016 is appropriate because (1) we used year as a control variable in the regression model; therefore, any differences in average cost across the 2 years is accounted for, and (2) we are using the model to estimate the multiplicative adjusters, not the base rate. MedPAC's main concern appears to be with changes in *average* treatment patterns between 2012 and 2013, not with changes in the *relative* costs associated with different patient characteristics, and the multiplicative adjusters reflect relative costs.

Comment: Several dialysis organizations pointed out that variation in the average facility cost per treatment derived from cost reports is not directly associated with variation in patient characteristics and because of this, the variable concepts for the payment adjustments cannot be measured by the cost report data. One large dialysis organization (LDO) stated they are very concerned that CMS believes it is appropriate to use ''total facility cost'' derived from the ESRD cost reports for the development of patient-level adjuster values. The LDO stated that the overall cost report data cannot be directly linked to any specific patient characteristic and that these data only provide information on total costs to operate a facility, which are generally a reflection of the number of patients the facility serves, management capabilities, and geographic location, not specific

patient characteristics. The commenters believe analysis of facility cost reports does not yield conclusive observations regarding individual patient characteristics. They recommend that CMS refrain from using cost report data to develop patient-level adjusters because they believe cost reports are only reliable for determining facility characteristics for use in developing the facility-level adjusters, such as the low-volume adjuster.

Response: We believe that the two-equation regression methodology is appropriate and has successfully estimated statistically significant patient- and facility-level payment adjusters. Below we provide an explanation as to how the two equations work together to derive the payment adjusters.

Within the cost report, we start with using the worksheet level detailed data and the total cost per treatment that is reported. Then we construct the average cost per treatment for each ESRD facility. At this point, we recognize that corporate costs may not be allocated to facilities in a uniform fashion across dialysis organizations. This variation in cost accounting creates unwanted variation in the cost report data. The control variables discussed below help account for these cost variations.

Next, we attach the distribution of patient characteristics at the facility-level to the cost at the facility-level. For example, for age, we would take the percentage of patients in each of the age categories at the facility level and attach that to the facility's average cost. There is one observation per facility, not one per patient. Stated differently, it is not the facility characteristic that is being attached to the patient, but rather the average case-mix characteristic being attached to the facility. Specifically, the observation is a facility year. The dependent variable is the average cost per treatment across all the treatments provided by that facility in that year. The case-mix factors that are being used to develop multipliers are also aggregated at the facility level from claims. For example, for BSA, it is the average BSA for all the patients treated at the facility during the year. The model evaluates whether facilities that have a disproportionate share of a certain characteristic (for example, high BSA) have higher/lower costs than facilities that have a smaller share of patients with those characteristics. For several of these characteristics, variations across facilities in the average values across all of their patients do predict CR costs.

We believe that this method along with the control variables described below allows us to distinguish variation in cost per treatment in the cost reports from variation arising from treatment volume and corporate policies. We note that differences in cost related to certain facility-level (aggregate) case-mix factors (patient age and body size) have been statistically estimated in the models that underlie the BCMA composite rate payment system implemented in 2004, the ESRD PPS implemented in 2011, and the CY 2016 ESRD PPS proposed rule. All of these models use the same basic methodology and have not come under this level of scrutiny in the past, which could indicate that it was accepted by the dialysis industry as an appropriate method for estimating cost variation.

The facility control variables of volume and ownership-related differences serve as proxies for the factors raised by the commenters. As proxies, they serve to not only adjust out their correlation with reported cost per treatment, but also ensure that the multipliers for the patient characteristics are not biased. The goal is to eliminate bias occurring by any existing correlations between patient characteristics and the control variables. For example, it is expected, due to sheer volume, that the LDOs have greater buying and negotiating power for drugs and supplies than a SDO or independent dialysis organization, but we do not have access to that information for our analysis in the model. For precisely this reason, we use control variables such as ownership because we do not have access to proprietary measures for factors such as purchasing policies raised by the commenter.

Comment: Several LDOs and a national association of ESRD stakeholders expressed concern that CMS and its contractor used statistical methodologies and identified adjuster variables in a manner that cannot produce valid or reliable adjuster values. One commenter stated that statistical methods are only valid if the data to which they are applied are a fit to the methods. The commenter further explained that statistical methods applied to data that do not meet the requirements for reliability and validity will produce results that are not accurate, may not be meaningful, and can be volatile from year to year. This commenter claimed that the fundamental requirements of a regression model were not met in the analyses used to design the ESRD PPS payment adjusters. The commenter further stated that to produce valid and reliable results, a regression analysis must be based on a sound research design and must adequately address the assumptions made by the mathematical properties of the regression analysis. They then provided the major assumptions that they claim underlie regression methods and noted that these assumptions are not valid for the CY 2016 proposed rule adjusters.

We address each core assumption that the commenter referred to in the next four comments and responses. Our general response is below.

Response: We acknowledge that the concerns raised about the regression model are reasonable concerns to have about any regression model. However, we disagree with the notion that the existence of these concerns implies that the analyses ''violate the core assumptions for a valid analysis.'' No regression model using real data conforms perfectly to the textbook ideals of a model that includes every potentially relevant variable, each of which is measured perfectly and perfectly represents the concept it is trying to measure, and is uncorrelated with any other variable of interest. We acknowledge that our regression analysis has limitations with regard to issues such as data availability, as does every regression model. We have provided responses to the wide variety of criticisms regarding the regression approach, data, etc., and we believe these responses support a model that is valid and stable. We believe we have selected an approach that mitigates such concerns as much as is feasible, and yields valid results, and that the model we are using most accurately aligns payment with resource use and accounts for both case-mix and facility adjustments in the most accurate way possible for a real-life scenario.

Comment: Commenters stated that the two-equation regression analysis used to produce the adjustor values is not correctly specified and stated that correct specification requires that all variables be statistically significant or theoretically related to the dependent variable in the regression model. Commenters further explained that correct specification requires that all variables that could predict change in the dependent variable (that is, the cost per treatment in the first equation, cost of separately billed items in the second equation) were included in the model. The commenters also stated that correct specifications require that the coefficients of the independent variables (the value assigned to the adjuster as a result of the regression) are assumed to not change during the period of analysis. They contend that if a regression model is not correctly specified, the results will be biased and

will not reflect an accurate impact of the independent variables on the dependent variable.

The commenter noted that the process for selecting variables and evaluating them for inclusion in the two-equation regression analysis was not comprehensive and there is reason to believe that the variables selected were not those that drive cost variation. The commenters indicated that the methods that CMS and its contractor used appear to produce results that cannot be directly linked to costs of providing dialysis care and are not directly linked to analysis of underlying patient clinical characteristics. Specifically, the commenters have indicated to us that our model is not capturing those characteristics that they see as having an effect on their cost, namely the ambulatory status and cognitive abilities of the very young and the elderly; cardiovascular instability or diabetes-related limb amputations; and, the extra time, supplies, and infection risk of central venous catheters. One dialysis organization provided the following list of drivers of variation in patient treatment costs, some of which overlap with the other commenter's list: use of central venous catheters, frailty, obesity, ambulatory status, cognitive capabilities, characteristics, conditions, and illness or race or ethnicity that are associated with an increased need for ESAs or vitamin D, chronic inflammation (difficult to define by specific disease), infection, chronic gastrointestinal bleeding, and myelodysplasias. They also claim that no independent research is referenced to support the use of those variables that are included.

Response: We believe that the commenter is referring to the reasoning and testing of different variables that were or were not included in the two-equation regression analysis used for the CY 2011 ESRD PPS final rule. The basic modeling approach for the ESRD PPS has been subjected to extensive development and testing for over a decade. Using cost report data, the composite rate equation development dates back to the work supporting the BCMA composite rate payment system implemented in 2004. In the development of the final rule for the 2011 implementation of the ESRD PPS, the two-equation approach was extensively tested and documented (in the Technical Report), along with testing many variables. We agree that many of the suggested payment variables may have an impact on treatment costs; however, adopting these suggestions would require additional reporting by ESRD facilities as to patient diagnoses or conditions. With regard to the cost drivers associated with race and ethnicity, which are related to an increased need for ESAs, we note that renal dialysis service drugs and biologicals are eligible outlier services, and as such, the outlier policy could pick up part of the cost of increased use of ESA and Vitamin D. We discuss race and ethnicity in the CY 2011 ESRD PPS final rule (75 FR 49108 through 49115) and provide detail on why we did not finalize those characteristics as payment adjustments.

The refinements focused on using more recent data, which reflect changes in practices and incentives under the ESRD PPS. We believe that the information that the commenter is referring to with respect to testing variables is available in the Technical Report developed by UM–KECC. In addition, we have provided theoretical reasons why the chosen variables could influence patients' care requirements throughout the CY 2011 and 2016 ESRD PPS final rule's preamble language where we discuss the analytical work behind each adjustment factor, which is also available in the Technical Report. We note that all of the adjusters have demonstrated statistical relationships to the dependent variables (average cost per treatment for composite rate services and the average Medicare Allowable Payment (MAP) for previously separately billable services) as evidenced by the results of the model. All patient-level variables (age, comorbidities, body surface area/body mass index, onset of dialysis) have been reviewed by expert clinicians and all facility-level variables (low-volume payment adjustment and rural adjustment) have been reviewed by health economists. These subject matter experts have opined that the two-equation model is statistically sound and appropriate for estimating cost variation for ESRD facilities. We appreciate the examples commenters provided that communicated to us the characteristics they consider to be related to increase in cost in furnishing dialysis. In order to capture most of the characteristics that were provided by commenters (for example, ambulatory status or cognitive function), we would need to develop ways for the information to be submitted. We will keep these comments in mind for future refinements.

As we discuss above, the primary purpose of the refinement was to test the assumption that the values had not changed since 2006 through 2008, and to refine the payment model to account for any changes that had occurred. Therefore, we developed adjusters using more recent data that were derived under the current payment system rather than continuing to use payment adjusters derived in the past. In addition, we analyzed rural areas and are finalizing a rural payment adjustment which is discussed in section II.B.1.d.iii.

Because we used updated data, we would expect the coefficients to have changed between 2006 through 2008 (the time period over which the current model was estimated) and 2012 through 2013 (the time period over which the proposed model was estimated). In fact, while the exact multipliers have changed overall slightly, the basic relationships (for example, U-shaped effect of age, higher costs soon after ESRD incidence) have been quite stable. With respect to referencing independent research to support the use of the variables in the model, the 2008 Report to Congress or Technical Report cite what was available in the literature at the time.

We do not have any reason to expect that the coefficients changed between 2012 and 2013. As noted by MedPAC, practices were still changing somewhat, but it is not clear that this would necessarily create any meaningful bias in the coefficients. As noted in response to MedPAC's comment above, the model controlled for year (that is, adjusted for the mean difference between the 2 years) therefore any difference in average costs across the 2 years is accounted for. Notably, when the model is estimated on a single year of data, the multipliers do not change appreciably. However, the preference is for using 2 years of data because doing so stabilizes the estimates for the facility-level composite rate model.

Comment: The next core assumption that the commenter expressed concern about was regarding the independence of observations. Specifically, the commenter stated that in a correctly specified regression model, the observations are uncorrelated with each other, which means that all treatments are assumed to be independent of each other. The commenter stated that in the ESRD context, treatments occur in a sequence linked to an individual patient such that treatment cost for one treatment may be related to prior treatment, the duration between treatments, events that interrupt treatments, such as hospitalization, and the patient's health status at the time of treatment. Therefore, treatments are not independent of each other and thus the assumption is not valid under the ESRD PPS model. The commenter specifically indicated that if CMS and their contractors used the ordinary least

squares test, the results of treatments not being independent of each other will be that it is no longer possible to trust significant tests. In addition, the commenter stated that if observations are, in fact, related as is the case with dialysis treatments, then this correlation between observations should be modeled in the regression using generalized least squares (another test used during the development of a model). The commenter claimed that they found no documentation to suggest that this method was used.

Response: It is our understanding from the comment that the commenter believed the unit of analysis (or observation as they labeled the term) in the model was a *dialysis treatment.* However, the unit of analysis for the two-equation regression analysis is not observed treatments (for example, a full year patient on thrice weekly dialysis could contribute up to 156 observations to the model each year), rather, it is each patient-month level. Specifically, the SB models are estimated at the patient-month level, not the treatment level. Therefore, there is a separate observation for each patient month, rather than for each treatment. In prior analyses, using 3 years of patient-month level data from 2006 through 2008, the effect of the correlation within patients was tested and it did not impact results. In addition, the primary concern from correlated (or clustered) observations is that the standard errors would be underestimated, not that the coefficients would be biased. The SB models have a very large number of observations and consequently almost all payment variables (and all that have large multipliers) are not of marginal statistical significance. Therefore, we believe that our unit of analysis, the patient-month, does not violate a core assumption of a valid analysis. A more detailed discussion on the unit of analysis, that is, patient-month, for the ESRD PPS model is available in the Technical Report beginning on page 39.

Comment: The next core assumption that commenters expressed concern about was regarding random error. Specifically, the commenter stated that a correctly specified regression assumes that there is not random error built into the independent variables. The commenters claimed that there is considerable error in the cost report data used and, as a result, the payment adjustments are biased and do not reflect the effect of the independent variable on the dependent variable. The commenter further explained that there are large amounts of missing data in the fields that are rolled up into the total cost field used in the analysis. In addition, the commenter stated that CMS has not disclosed how it handled trimming data for unbelievable values and other types of error. Lastly, the commenter indicated that hospital cost reports are frequently highly inconsistent with freestanding facility cost reports and are often missing, or have large amounts of missing data. The commenter stated that without addressing the known level of error in the data source, the assumption that the data are error free is violated. However, the commenter noted that the claims data used may meet the condition for this assumption.

Response: Our understanding of the comment is that the commenter believes that the independent variables are derived from the cost report. While we link patient characteristics to the cost at the facility level using cost report data (as we discuss above), the independent variables that are used as payment adjusters are derived primarily from claims for patient characteristics and other CMS data sources for facility characteristics (for example, size, low-volume status, rural status, organizational characteristics). We believe that the commenter's concern about accuracy is about the cost per treatment measure derived from the cost reports for use in the composite rate equation. That is, the error to which they refer is on the dependent variable (average cost per treatment for composite rate services), not on the independent (or predictor) variables (case-mix and control variables) as they state.

We note that classical measurement error (that is, when a variable of interest—either an explanatory or dependent variable—has some measurement error independent of its value) on independent variables can bias coefficients (typically downward, implying that estimates of the effect would be conservative). For example, classical measurement error on a low BMI could bias the coefficient downward, resulting in an underestimation of the additional resource use needed by the thin, frail patient. On the other hand, classical measurement error on the dependent variable affects the precision of the estimates of the coefficients on the independent variables due to the extra ''noise'' in the data, but does not bias the coefficients. Further, one reason for including a number of facility-level control variables in the model is to control for some of the facility or organizational factors that might contribute to variation in cost per treatment that arises for factors other than variation in patient characteristics.

The commenters assert that they have data that demonstrate the factors, such as profit status and dialysis organization affiliation have no impact on composite rate cost per treatment on the cost report. This evidence was not presented in the comment and we would find it helpful to have this data shared with us. While they assert that factors such as financial policies and negotiated medication prices do matter, these are precisely the factors that would vary across organizations. We use the differences such as affiliation and hospital-based status between large, medium, and small dialysis organizations as proxies to capture these differences. Unless a mechanism is developed to require that all dialysis organizations share information such as their acquisition costs for dialyzers and negotiated medication prices with CMS, which they may consider proprietary, it would not be possible to adjust directly for those items in the model.

Comment: The last core assumption that commenters expressed concern about was correlation of variables. Specifically, commenters stated that the independent variables should not be correlated with each other. The commenters find that there is considerable correlation among the independent variables which reduces the accuracy of the adjustment factor. A medium dialysis organization (MDO) commented that use of the BMI and BSA is a concern as they are both variables for the same patient characteristic and essentially cancel each other out. They stated that preferably, these variables should not be used as the independent variables for the case-mix adjusters.

Response: It is correct that correlation between variables makes it more difficult to statistically distinguish their independent effects on the dependent variable, but only very high correlations necessarily render it impossible. As long as the variables have some independence from each other (one does not precisely predict the other), it may still be possible to estimate their separate associations with outcomes.

With respect to BSA and low BMI, these variables represent different characteristics that have individual effects on cost. In particular, BSA (which is a continuous variable that increases as the patient's body size rises) is empirically associated with higher composite rate costs. The fact that larger patients on average generate higher composite rate costs may reflect the longer dialysis time which is required to effectively dialyze larger patients. In contrast, the low BMI categorical variable identifies

particularly frail patients, that is, those with BMI less than 18.5. This measure of frailty is empirically associated with higher separately billable costs. These very frail patients require more expensive drug therapies.

While BSA is negatively correlated with low BMI, the correlation is not perfect. BSA and the low-BMI indicator variables measure related, but different concepts and complement each other (that is, small and frail are not the same). The low-BMI multiplier helps avoid the potential of payments not reflecting the higher costs of caring for frail patients. Therefore, elimination of the low-BMI adjuster could reduce frail patients' access to care by encouraging perverse incentives in facilities, who may try to avoid such patients if their costs are not reflected in the payment system. If there was only a BSA adjustment, then the heavier beneficiaries requiring more dialysis time would be accounted for by the facilities receiving the additional payment, with the lighter weight beneficiaries not receiving as much, to the detriment of those at the lowest end of the scale, the thin and frail. In other words, having the low-BMI adjustment in opposite direction of the BSA adjustment for small, frail patients is the intended effect. Dropping the low-BMI adjuster could place frail patients at increased risk of being denied access to care if there is only a downward adjustment for small BSA.

Further, we note that even if BSA and BMI are strongly correlated when measured as continuous variables (a variable that can take any value between two numbers), this is not how they appear in the model. Only BSA is entered continuously. BMI is entered as a discrete indicator variable for being below the accepted cutoff indicating potential undernourishment/frailty, which is at the extreme of the distribution. The correlation between that discrete indicator of an extreme value for BMI and the entire continuous range of BSA is not exceptionally high. In short, these two variables complement one another in the payment model since low-BMI is a proxy for frail and malnourished patients and BSA is a proxy for time on machine and other high resource use. Similarly, while there is some correlation between rural status and low-volume status, the other specific instance of co-linearity raised by the commenters, those are both dichotomous indicators and there are substantial numbers of facilities having each of the four possible combinations of the two variables. If there were no low-volume, non-rural facilities, and no non-low-volume rural facilities, it would be impossible to statistically distinguish the low-volume effect from a rural effect, but in fact many such facilities exist. We discuss BSA and low BMI and facility-level adjustments in greater depth in section II.B.1.c.2 of this final rule.

Comment: Commenters stated that because the adjuster variables explain less than 10 percent of the variation in cost, the model should have been reevaluated before being proposed. They explained that the R-squared results for the proposed adjusters were not provided, despite being requested.

Response: Because the model is estimated as two equations at different units of analysis (facility and patient-year), there is not a single, accepted method of calculating a combined R-squared. R-squared values have been provided for each equation. The coefficient of determination, denoted R^2 or r^2, is a number that indicates how well data fit a statistical model—sometimes simply a line or a curve. An R^2 of 1 indicates that the regression line perfectly fits the data, while an R^2 of 0 indicates that the line does not fit the data at all. This latter can be because the data is utterly non-linear, or because it is random. It is a statistic used in the context of statistical models whose main purpose is either the prediction of future outcomes or the testing of hypotheses, on the basis of other related information. It provides a measure of how well observed outcomes are replicated by the model, as the proportion of total variation of outcomes explained by the model. Obviously, higher R-squared values are preferred, as this would reflect greater ability to predict cost. However, many case-mix adjustment models do not achieve high R-squared values because medical costs inherently have a large random component. We disagree with the commenter's suggestion that a model must explain 10 percent of the variation, and have had our experts concur with the validity of the two-equation model. There was no concurrence among the experts regarding a 10 percent statistical cutoff rule for variance explanation in a model.

What is more significant is that the payment adjusters have a statistically significant effect on costs, and that that effect is meaningful in magnitude (that is, large enough that failure to account for it would results in payments substantially below costs). If the model demonstrates that there are characteristics of individual patients that are systematically and meaningfully related to costs, adjusting payments for those characteristics can be important independent of the model's overall R-squared, regardless of whether the overall R-squared is high, medium or low. It is important that adjustments be made for the organizations that care for a disproportionate share of resource-intensive patients, particularly if those organizations do not have many dialysis units across which they can diversify that risk to receive payment that reflects the characteristics of their patients that are related to cost of care. Equally important is the prevention of access to care problems for patients with those characteristics. Failure to provide adjustments could result in access problems, such as incentives for cherry-picking, and these issues could occur regardless of the size of the dialysis organization.

Comment: Commenters had specific concerns about how variables were chosen for the two-equation regression analysis and expressed concern that exaggerated statistical significance of variables based on a universe, not a sample, has resulted in adjusters with questionable statistical or clinical significance. The commenter expressed concern that the large number of facilities and treatments used in the two regressions has resulted in exaggerated statistical significance of coefficients. They further explained that this is because coefficients become more statistically significant as the size of a *sample* increases and statistical significance is most useful to evaluate selection of variables when actual samples are being used. The commenter claimed that CMS uses as much of the universe as it can, rather than having statistically sampled the universe. They stated that the result of this is statistical significance as used by CMS no longer has the meaning it does with actual samples. The commenter pointed to the 2008 Report to Congress and stated that the age categories 45 to 59 and 70 to 79 were not significant at the .05 level. They indicated that given the large sample size, if age were an independent driver of cost, they would expect a greater level of significance. The commenter noted that none of these specifications were disclosed for the updated regressions used to estimate the proposed 2016 payment adjusters.

Response: In the work leading to the CY 2011 ESRD PPS payment rule, this issue was addressed. One variable selection criterion was that a comorbidity would be considered for a payment adjustment if its relationship to cost was both statistically and economically significant. As noted by the commenter, even a very small multiplier could be statistically significant due to the large sample. All of the proposed comorbidity adjusters

have economically meaningful multipliers.

As noted by the commenter, the interpretation of statistical significance changes when the data include a universe rather than a random sample. Essentially, when the universe is used, the coefficients can be interpreted as being perfectly accurate (they perfectly reflect the universe, because they are derived from the universe). However, statistical significance remains relevant for two reasons. First, it is a tool to assess the closeness of the relationship between the predictors and outcomes. Second, and more importantly, even a near universe of claims from a given time period represents a sample of time periods (for example, 2012 and 2013 claims are being used to project relationships in 2016). The commenter's solution, to use less data than are available in order to estimate the relationships, sacrifices precision in the estimates. As noted at the beginning of this response, we prefer to use all the data and assess whether the relationships have sufficient economic size to potentially warrant adjustment. For example, a comorbidity could be associated with a trivial 0.1 percent increase in costs that could nonetheless be statistically significant due to the very large sample size. Such a comorbidity would not have been chosen for inclusion in the payment model.

Comment: Commenters stated that because of the poor fit of the model to appropriate data, the high level of correlation among the adjuster variables, and the many violations of assumptions required for valid regression, they do not believe that this regression model can be fixed. Due to these concerns about the methodology and based upon their clinical experience, they recommend that we retain the current (CY 2015) age adjuster and payment multipliers rather than adopt the proposed modifications; retain the CY 2015 low-BMI adjuster to address underweight patients and establish a high BMI adjuster to address overweight patients tied to the NIH guidelines for defining overweight patients using BMI rather than applying the BSA adjustment; retain and recalculate the onset of dialysis adjustment; remove all comorbidities adjustments; and retain the LVPA modifications and develop a two-tiered LVPA in place of the rural adjustment. Several commenters proposed estimating new multipliers for some factors (for example, onset of dialysis, obesity, two-tiered rural adjustment) while retaining some current adjusters.

One LDO's overall concern is that any adjuster must be clinically relevant and serve the purpose of ensuring that the ESRD PPS does not discriminate against high-cost patients. They believe that several of the adjusters as currently structured do not meet this end goal. They requested that we eliminate a number of adjusters for CY 2016 (comorbidities, age, and body mass index (BMI)/body surface area (BSA)) in their current constructs because they are not based on clinical data, are executed ineffectively or inaccurately, or they do not represent actual incremental facility costs. They believe that absent the ability to put needed changes in place for CY 2016, elimination of these adjustments during the upcoming year will provide CMS the time needed for re-analysis of the true impact. The LDO states that a 1-year hiatus for all adjustments with the exception of the onset of dialysis and low-volume adjusters (as defined in 2015), true drivers of incremental costs, will allow the Agency to take the necessary time to implement improvements that reflect the current dialysis unit cost reality.

Response: We continue to believe that moving forward with an updated model aligns with our goals for the prospective payment system in establishing accurate payments and safeguarding access for Medicare beneficiaries. As noted above, we modeled the ESRD PPS using methodologies that have been tested since the Basic Case-Mix Adjusted (BCMA) composite rate payment system and in using the most recently available data, we made our best estimate for predicting the payment variables that best reflect cost variation among ESRD facilities for furnishing renal dialysis services to a vulnerable population of patients. This refinement uses data that illustrates a fully bundled prospective payment system and reflects the practice patterns under such environment. We believe that it would not be appropriate to both perpetuate certain payment adjusters into the future that were developed using pre-PPS data and update the other adjusters using ESRD claims data and cost reports from 2012 and 2013.

While we appreciate the suggestions from commenters, we are unsure how the new adjusters would be estimated using the commenter's proposals. They did not specify whether we would force the retained CY 2015 multipliers to take on their old values when estimating the new model or allow the retained variables to take on the new values they have using the updated model, but only use new values for the other factors. We believe the proposed approach of blending in some unspecified way multipliers derived from different time periods and different statistical models into a single payment system would not provide a meaningful empirical basis for the payment model.

Comment: A national association of kidney patients expressed concern that because of the data sources such as unaudited cost reports and the two-equation methodology used (as discussed throughout the comments and responses above), the payment for the patient-level adjusters are not serving the policy intention of protecting access to care for beneficiaries who are perceived to be more costly. The association's health professional membership, which includes nephrologists, nurses, advanced practitioners, dietitians, and social workers have stated that while age is not always a predictor of costs, it is a legitimate proxy for higher costs associated with older patients. Similarly, underweight patients and overweight patents also contribute to increased costs to the dialysis facility. However, the rationale for these higher costs is not necessarily always reflected in claims data and dialysis facility cost reports because patients, that is, the overweight, the frail and the aged, are not distinct categories in the cost reports or the claims, and typically require more staff time devoted to them.

Response: We agree with the commenter that there are relationships of cost to age and body size. The age, BSA, and low-BMI adjustments in the CY 2016 ESRD PPS proposed rule incorporate those adjustments based on what can be statistically estimated from facility-level data on dialysis costs and patient-level data on costs of formerly separately billable items. These obviously and necessarily represent average relationships, while, as the commenter notes, for example, age is associated with cost but not necessarily for every patient. We believe that the age adjustments may serve to capture cost variation that is not captured by the other adjustments. As mentioned in a previous response, we would ideally like to have cost data at the patient-level rather than the facility-level, but data limitations preclude us from estimating that relationship at the patient-level. Rather, the estimated relationship is between average patient characteristics (for example, percentage in each age group, average BSA, percentage at onset of ESRD) and average cost at the facility. Failure to adjust for these empirically derived relationships between case-mix and costs provides facilities with an incentive to cherry pick patients with low cost characteristics and avoid patients with high cost characteristics.

Comment: A patient group noted that in proposing the new age adjusters, CMS engaged in *data dredging,* the practice of analyzing large volumes of data to seek statistically significant relationships, without being guided by any hypothesis or explicit theory about behavior.

Response: The original modeling effort to establish the 2011 payment adjusters for the bundled ESRD PPS examined a large number of comorbidities and patient characteristics that could be related to costs. The examination was broad as the impact on cost could theoretically occur through several channels, both direct (for example, more staff effort in the dialysis unit) and indirect (for example, patients with certain conditions are more likely to be hospitalized or otherwise skip treatments, which could increase costs per treatment delivered due to greater unanticipated holes in facilities' schedules, as well as other research published by the contractor in conjunction with this project that identified that hospitalized patients used more injectables per treatment on an outpatient basis, presumably making up for smaller or missed doses away from the facility). As described in the 2008 Report to Congress and Technical Report, other criteria were applied to guard against *data dredging.* Notably, comorbidities with a very small relationship to cost could still be statistically significant in the SB model due to high degree of statistical precision allowed by the very large sample size; such variables were excluded as payment adjusters. They were deliberately excluded to avoid *data dredging.*

Comment: A patient group commented that the methodology has taken the characteristics of groups of patients at the facility-level to make inferences about individual patients. They indicate that it appears this was done solely by reason of the convenience of having cost data available at the facility-level, but not at the patient-level.

Response: This is an inherent limitation of the currently available data, not a choice made for convenience. If we had access to cost information at the patient-level for formerly CR services, we would have estimated that model at the patient level rather than at the facility level. As we discuss above, such information is unavailable, primarily because ESRD facilities do not report their actual charges or resource costs for various renal dialysis services formerly paid under the composite rate on their claims, and facilities do not report charges for cost-relevant elements of the dialysis treatment, such as their charges for the dialysis filter which would reflect their policies regarding reuse of dialysis filters and other supplies. If the ESRD facilities reported charges in a way that was sensitive to variations in actual resource used across their individual patients, we could use reported charges adjusted by the cost-to-charge ratio developed from cost reports to estimate their cost for the ESRD PPS bundle of services. Such an analysis would infer the effect of patient characteristics on costs based on how facility average cost per treatment varies with the average characteristics of patients within the facility. This is an acknowledged limitation, but it arises by necessity given the nature of the available data.

Comment: A professional organization commented with the hypothesis that in the current time of decreased ESA use, the original set of conditions, such as age, comorbidities, BSA/BMI and onset of dialysis, likely has less influence on overall dialysis facility expenses. They commented similarly that it is possible that certain high risk patients, who previously made relatively minor contributions to overall costs, now have a larger cost impact and provided the example of patients with mental illness, lower socioeconomic status, and fewer resources available at home, which may contribute in different ways to higher resource consumption and expenditures for delivery of dialysis care. Additionally, patients initiating dialysis in the hospital with multiple medical comorbidities and complex disease states also can require more resources in order to coordinate care. The complex interactions among multiple comorbidities and social circumstances are not captured through current risk assessment tools.

Additionally, the organization points out that the focus of the current case-mix regression models ignores several other important dialysis facility costs and could limit access to care. The organization stated that when patients (either due to non-adherence, mental illness, social stress, frequent hospitalization due to severity of their illness or other identifiable but unadjusted-for causes) are either unable to or refuse to attend outpatient dialysis treatments, facilities do not receive payment. The fixed costs borne by the facility for a patient missing dialysis treatment as well as the opportunity costs associated with the lost revenues that could have been collected by a facility if a different patient who would not have missed dialysis had instead been dialyzed are not captured in the case-mix adjustments.

To maximize access to care for high risk patients, the organization urged CMS to explore methods of case-mix adjustment that further refine characterizing high risk patients. They also suggest that the costs associated with meeting more recent QIP goals in high-risk patients as well as the cost of potential QIP penalties in patients for whom facilities are unable to improve QIP-related metrics despite appropriate efforts to do so are currently not reflected in the case-mix adjustments. They urged consideration of these costs in order to ensure access to care among high-risk patients and urged CMS to actively monitor whether dialysis facilities decline to care for higher risk patients.

Response: While it may be true to some extent that in the current time of decreased ESA use, the original set of conditions has less influence on overall dialysis facility expenses, all of the ESRD PPS payment adjusters continue to be predictive of higher costs. However, the overall multipliers reflect the decreased use of injectable medications through the weighting of the separately billable equation. While we are unsure about what risk assessment tools the commenter is referring to, we agree that the current model does not capture the conditions suggested by the commenter primarily because conditions that may lead to missed treatments are not captured on ESRD facility claims or in cost report information, the two sources of data currently available for use in the regression analysis. In addition, ESRD facilities have reported significant problems in obtaining diagnostic information for the comorbidity adjustments as discussed in section II of this final rule, and would likely have similar problems in obtaining the information suggested. However, some of the adjusters in the model (for example, onset, age) are likely related to missed treatments, and their multipliers will partially reflect the effect of missed treatments on costs.

For future refinement, we are willing to explore what information would have to be reported by ESRD facilities in their claims in order to assess the impact of commenters' suggested factors on the regression. With respect to the comment regarding consideration of costs that are associated with meeting QIP goals in high-risk patients, it would not be appropriate to include the cost of QIP penalties in the case-mix adjustments. However, as we stated above, we would be interested in obtaining more information from ESRD facilities on

those specific characteristics mentioned in the comment so that we could analyze the information for future refinements.

Comment: One commenter requested that CMS only provide adjusters that protect patient access.

Response: The most recent regression analysis confirms that the payment adjusters implemented in 2011 continue to be indicators of high cost patients. For this reason, we continue to believe that the case-mix and facility adjustments are necessary to protect access to renal dialysis services for high cost patients. All of our adjusters were developed to serve as patient protectors. The patient adjusters (case-mix) recognize the higher costs associated with dialyzing/treating patients with co-morbid conditions that facilities may not be willing to otherwise treat because of the monetary loss. The facility-level adjusters protect patient access by providing additional monies to facilities in more economically or geographically restricted areas that encourage their opening and operating to serve those beneficiaries who may not otherwise have access.

For the reasons described above, we continue to believe that the two-equation regression methodology is sound and that it confirms the continued relevance and significance of the case-mix and other adjustments. More importantly, finalizing the regression methodology is appropriate so that future payments reflect the bundled environment under the ESRD PPS with the associated drop in the utilization of ESAs, other renal dialysis service drugs and laboratory testing. Accordingly, we are finalizing the use of the two-equation regression methodology to update the payment adjustments as proposed.

c. Analysis and Revision of the Payment Adjustments

As required by section 632(c) of ATRA, we have analyzed and are finalizing revisions to the case-mix payment adjustments below. We are also finalizing revisions to the facility-level adjustments for uniformity as described below.

i. Adult Case-Mix Payment Adjustments

1) Patient Age

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account a patient's age. In the CY 2011 ESRD PPS final rule (75 FR 49088), we noted that the basic case-mix adjusted composite rate payment system in effect from CYs 2005 through 2010 included payment adjustments for age based on five age groups. Our analysis for the CY 2011 ESRD PPS final rule demonstrated a significant relationship between composite rate and separately billable costs and patient age, with a U-shaped relationship between age and cost where the youngest and oldest age groups showed the highest costs. As a result of this analysis, we established five age groups and identified the payment multipliers through regression analysis. We established age group 60 to 69 as the reference group (the group with the lowest cost per treatment) and the payment multipliers reflect the increase in facility costs for each age group compared to the reference age group. We established the group with the lowest cost per treatment as the reference group in order to avoid age adjustments with negative multipliers. We proposed and finalized payment adjustment multipliers for five age groups; ages 18 to 44; 45 to 59; 60 to 69; 70 to 79; and 80 and older. We also finalized pediatric payment adjustments for age, which are discussed in section II.B.1.e. of this final rule.

Commenters and stakeholders were largely supportive of a case-mix adjustment for age when the ESRD PPS was implemented. We noted in our CY 2011 ESRD PPS final rule (75 FR 49088) that several commenters stated that age is an objective and easily collected variable, demonstrably related to cost, and that continuing to collect age data would not be burdensome or require systems changes. In addition, a few commenters requested that CMS consider an additional adjustment for patient frailty and/or advanced age (75 FR 49089). In the CY 2011 ESRD PPS final rule, we responded to these comments by noting that we included an age adjustment for patients 80 years of age or older, but that advanced age and frailty did not result in the identification of additional age groups for the application of case-mix adjustments based on age. In addition, we noted that the analysis did not identify a separate variable for patient frailty, as this would be very difficult to quantify.

As we discuss in the CY 2016 ESRD PPS proposed rule (80 FR 37815), the analysis we conducted to determine whether to revise the case-mix payment variable of patient age demonstrates the same U-shaped relationship between facility costs and patient age as the analysis we conducted when the ESRD PPS was implemented, however, the reference group has changed to age group 70 to 79, and we note significantly higher costs for older patients. For this final rule, we continue to believe that the regression analysis performed on CY 2012 through 2013 Medicare cost reports and claims has appropriately recognized increased facility costs when caring for patients 80 years old or older, and that this adjustment accounts for increased frailty in the aged. Age may serve as a proxy for several characteristics that cannot be easily measured and entered directly into the model. For example, younger patients may be more costly due to greater likelihood of skipped treatments, HIV infection, or drug dependence, while older patients might be more expensive due to greater likelihood of cognitive impairment or functional/mobility limitations.

The public comments we received on the proposed age adjustments and our responses are presented below.

Comment: MedPAC commented that through various revisions to the model, the empirically-determined lowest-cost reference group shifted from ages 45–59 in the CY 2011 ESRD PPS proposed rule, to ages 60 to 69 in the CY 2011 ESRD PPS final rule, and to 70–79 in the CY 2016 ESRD PPS proposed rule. They would expect that the relative cost of dialysis treatment across age categories would remain relatively stable over time. They expressed concern that such shifts indicate that the estimated factors are highly sensitive to the model's specification and that the model lacks robustness. They indicated that the two-equation approach might contribute to these results.

Response: As we explained previously, we do not agree with MedPAC. In both models using 5 age groups, costs followed a U-shaped pattern with age, with highest costs occurring in the 18 to 44 group, the second highest costs occurring in the 80+ group, and the lowest costs in the three middle groups. The only qualitative changes are that the U-shape is now a bit more pronounced (higher multipliers for the youngest and oldest group), and among the three middle groups, the lowest cost group shifted from 60 to 69 to 70 to 79. Notably, the cost difference between the three middle age groups in the original 2006 through 2008 model was very small, so the shift from one of those categories being singled out as the lowest cost (reference) group rather than another is not very meaningful. In other words, the middle groups were so close to each other in cost in the 2006 through 2008 model that having a different one of the middle groups being the lowest cost group in the 2012 through 2013 data is not surprising and does not indicate flaws in the model. Only small changes

in the data and the relationships between age and cost would be needed to cause such a change.

Comment: Two national dialysis organizations noted that the proposed change in the age adjustments is $7.47 per treatment to $19.36 per treatment, but that they are unable to identify any correlation that justifies a 159 percent increase for the age adjustments. They stated that the age adjuster randomizes payment, rather than targeting payments to patients with specific characteristics associated with higher costs. They recommended that we defer the change in the age adjustment and retain CY 2015 weights and values. An LDO, in analyzing its facility data, cannot validate a direct relationship between patient's age and cost of care. They do not believe it is appropriate to move forward with what they contend are arbitrary adjustments that they believe are not based upon analysis of specific clinical patient characteristics.

Response: As we explained previously, the current CY 2015 age values were derived from the same methodology applied to the refinement analysis but are based on pre-PPS data. Using updated data confirmed that age correlates with differences in resource use and that the age adjustments are not arbitrary. Rather, we believe the age adjustments reflect differences in health status that are not otherwise reflected in the ESRD PPS payment adjustments and support facilities treating patients in the youngest and oldest age categories who have higher per treatment costs on average. We believe retaining the current age values would not be appropriate because we have updated data available for analysis that reflects the changes in practice patterns that have occurred under the ESRD PPS. Additionally, we continue to believe the age adjustments are appropriate and do not believe they randomize payment. Rather they target payments primarily to the two highest cost categories: ages 18 to 44 and age 80 or older.

While we are uncertain as to how the commenter calculated an increase in the age adjustments of $7.47 per treatment to $19.36 per treatment, as we mentioned in the previous section, the payment multipliers were derived using an analysis that attached the distribution of patient characteristics at the facility-level to the cost at the facility-level. For example, for age, we would take the percentage of patients in each of the age categories at the facility-level and attach that to the facilities' average cost. Therefore, the payment multipliers represent empirical relationships derived from the national ESRD facility data, and target payment for patients in the various age groups according to their resource use and cost. Thus, we believe the multipliers are appropriate and not arbitrary.

Comment: An organization of home dialysis patients, a nonprofit dialysis organization, and an organization representing small and medium dialysis facilities expressed concern that the 11 percent age adjuster increase of $24.58 for patients 80 years and older may have the unintended effect of reducing the use of medical management of their kidney disease instead of dialysis. They are concerned that there will be an incentive to dialyze elderly people and not fully explore all options for treating their kidney disease. Commenters also noted that medical management of care may be the best option for the end of life care. They requested that CMS return the dollars withheld for this age category to the base rate to help provide the best care to all patients. An organization of nonprofit SDOs agreed and suggested that the increased cost of care for this age group may be due to patients who are not good candidates for dialysis who would benefit from medical management instead of dialysis to treat their kidney disease.

Response: We believe it vitally important for all chronic kidney disease patients to receive kidney disease education services as described in section 1861(ggg)(1) of the Act to discuss all treatment options, including medical management of their kidney disease with their nephrologist so that the patients have complete information about their treatment options. Decisions about whether to continue medical management of patients' kidney disease or to begin dialysis once the patients' condition has reached Stage V (ESRD) are made by the patient and their nephrologist. We do not believe that the best approach to accomplish the goal of ensuring appropriate management of elderly patients' kidney disease is to remove the age adjustments and to increase the base payment paid for all dialysis treatments. We are concerned that this approach, which would not recognize the full cost of caring for patients 80 years and older, could create access problems for those patients for whom dialysis is the best treatment option.

Comment: A national kidney association commented that their health professional membership, which includes nephrologists, nurses, advanced practitioners, dietitians, and social workers, have stated that while age is not always a predictor of costs, it is a legitimate proxy for higher costs associated with older patients. They pointed out that older patients are more susceptible to falls, requiring greater facility staff assistance to obtain their weights and assist them in and out of the dialysis chair. Commenters explained that elderly patients are also more likely to have a catheter, which increases the risk of bloodstream infections requiring antibiotics, blood cultures, and more frequent hospitalizations. They also tend to have more comorbid conditions, which could require frequent adjustments in the dialysis prescription and closer surveillance of the multitude of medication they may be on. Given this, it does not make sense that the age group of 70 to 79 would not have a payment adjustment while the 60 to 69 year old population would have a 7 percent payment adjustment.

Another organization commented that there should be an adjustment for patients aged 70 to 79 and that failure to adjust payments for patients in this age group implies that these patients require fewer services than those in the other age groups. They recommended that CMS provide more information about this counter-intuitive effect. An SDO questioned what has changed since implementation of the ESRD PPS in 2011 that would have resulted in such a shift in the reference group. An organization of nonprofit SDOs agreed and indicated that, as MedPAC suggests, it may be the result of the two-equation regression methodology or other factors in the model. The organization stated that the better course at this time is to leave the reference group unchanged pending further analysis and urged CMS to do so. Two nursing associations urged CMS to maintain the current reference group (ages 60 to 69) because in their experience, patients in the 70 to 79 age group often have greater needs and suffer more complications than younger adults.

Response: We agree with the comment that age is a legitimate proxy for higher costs associated with older patients that are not otherwise reflected in the model. As stated previously, we established a reference group that reflects the age group with the lowest cost per treatment and compared the cost per treatment for all other age groups to the reference group so that all the other adjustments for age would be increases in payment. In the regression analysis, we determined that the age group 70 to 79 is the group with the lowest cost per treatment on average, despite the fact that some patients in the group may have greater needs and high cost per treatment. With regard to the question about what changed since implementation of the ESRD PPS that would explain the shift in the age

reference group, we reiterate that, over time, there has been limited cost variation across the middle age categories and the change in the reference group does not indicate a flaw in the methodology.

Comment: An MDO questioned the payment multipliers for age for the outlier adjustment, which they believe were different from the payment multipliers when the original bundle was finalized. They indicated the multipliers were not listed in the CY 2016 ESRD PPS proposed rule, asked if the multipliers changed due to the regression, asked when the multipliers would be available, and questioned whether they would have an opportunity to comment before they are finalized.

Response: We believe that the commenter is referring to the coefficients that are derived from the separately billable model, which are used in determining outlier eligibility. Specifically, as discussed in the Medicare Benefit Policy Manual (Pub. 100–02, Chapter 11, section 60.D), the outlier payment computations use the case-mix adjusters for separately billable services to predict the per treatment MAP amount for outlier services. We provided the separately billable multipliers in the CY 2016 ESRD PPS proposed rule in Table 4 titled, CY 2016 PROPOSED ADULT CASE-MIX AND FACILITY-LEVEL PAYMENT ADJUSTMENTS (80 FR 37823) for the adults and in Table 5, titled, CY 2016 PROPOSED PEDIATRIC CASE–MIX PAYMENT ADJUSTMENTS (80 FR 37824) for pediatric patients. These multipliers have not changed and are reprinted in this final rule in Table 4 titled, CY 2016 ADULT CASE-MIX AND FACILITY-LEVEL PAYMENT ADJUSTMENTS for the adults and in Table 5 titled, CY 2016 PEDIATRIC CASE-MIX PAYMENT ADJUSTMENTS. The outlier policy is described in detail in section II.B.2.c. of this final rule.

After consideration of the comments, effective January 1, 2016, we are adopting the proposed age payment multipliers provided in Table 1 of the CY ESRD PPS proposed rule (80 FR 37815) and reproduced below in Table 1.

TABLE 1—CY 2016 FINAL PAYMENT MULTIPLIERS FOR AGE

Age	Final payment multipliers
18–44	1.257
45–59	1.068
60–69	1.070
70–79	1.000
80 +	1.109

2) Body Surface Area (BSA) and Body Mass Index (BMI)

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account patient weight, body mass index (BMI), and other appropriate factors. Through the use of claims data, we evaluated the patient characteristics of height and weight and established two measurements for body size when the ESRD PPS was implemented: Body surface area (BSA) and BMI. In our analysis for the CY 2011 ESRD PPS final rule, we found that the BSA of larger patients and low BMI (< 18.5 kg/m^2) for malnourished patients were independent variables in the regression analysis that predicted variations in payments for renal dialysis services. As such, we finalized two separate payment adjustments for body size in our CY 2011 ESRD PPS final rule (75 FR 49089 through 49090).

Commenters were supportive of BSA and BMI payment adjustments in 2011, noting that body size was a payment adjustment under the composite rate payment system, and that ESRD facilities would be able to capture this information on the claim form without any additional burden. A few commenters expressed concern regarding pre- versus post-dialysis weight. In response to these comments we clarified that a patient's weight should be taken after the last dialysis treatment of the month, as directed in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 8, Section 50.3.

For the CY 2016 ESRD PPS proposed rule, we analyzed both BSA and low BMI (<18.5kg/m^2) individually as part of the regression analysis and found that both body size measures are strong predictors of variation in payments for ESRD patients.

Body Surface Area (BSA)

Since CY 2005, Medicare payment for renal dialysis services has included a payment adjustment for BSA. The current payment adjustment under the ESRD PPS is l.020, which implies a 2.0 percent elevated cost for every 0.1 m^2 increase in BSA compared to the national average BSA of ESRD patients. The increased costs suggest that there are longer treatment times and additional resources for larger patients. Including the BSA variable improved the model's ability to predict ESRD facility costs compared to using BMI or weight alone.

In the CY 2011 ESRD PPS proposed rule (74 FR 49951), we discussed how we adopted the DuBois and DuBois formula to establish an ESRD patient's BSA because this formula was the most widely known and accepted. That is, a patient's BSA equals their Weight $^{0.425}$* Height $^{0.725}$* 0.007184, where weight is in kilograms and height is in centimeters. (DuBois D. and DuBois, EF. ''A Formula to Estimate the Approximate Surface Area if Height and Weight be Known'': Arch. Int. Med. 1916 17:863–71.) Once the patient's BSA is determined, the payment methodology compares the patient's BSA with the national average BSA of ESRD beneficiaries and computes the patient-level payment adjustment using the average cost increase for changes in BSA (per 0.1 m^2).

In developing the BSA payment adjustment under the ESRD PPS, we explored several options for setting the reference values for the BSA (74 FR 49951). We examined the distributions for both the midpoint of the BSA and the count of dialysis patients by age, body surface and low BMI. Based on that analysis, in our CY 2012 ESRD PPS final rule (76 FR 70244) we set the reference point at a BSA of 1.87 which is the Medicare ESRD patient national average BSA. Setting the reference point at the average BSA reflects the relationship of a specific patient's BSA to the average BSA of all ESRD patients. As a result, some payment adjusters would be greater than 1.0 and some would be less than 1.0. In this way, we were able to minimize the magnitude of the budget-neutrality offset to the ESRD PPS base rate. (For more information on this discussion, we refer readers to the CY 2005 Physician Fee Schedule final rule (69 FR 66239, 66328 through 66329) and the CY 2011 ESRD PPS proposed rule (74 FR 49951)). The BSA factor is defined as an exponent equal to the value of the patient's BSA minus the reference BSA of 1.87 divided by 0.1.

In the CY 2012 ESRD PPS final rule (76 FR 70245) and the CY 2013 ESRD PPS proposed rule (77 FR 40957), we stated our intent to review claims data from CY 2012 and every 5 years thereafter to determine if any adjustment to the national average BSA of Medicare ESRD beneficiaries is required. Although the CY 2012 claims showed an increase in the national average BSA, we did not implement an update in the CY 2013 ESRD PPS rule. Rather, in light of the requirement in

section 632(c) of ATRA that we analyze and make appropriate revisions to the ESRD PPS case-mix adjustments for CY 2016, we decided to incorporate the new national average BSA into the overall refinement of our payment adjustments that we are making as a result of that requirement.

In accordance with our commitment to update the Medicare national average BSA and because of the statutory requirement to analyze and make appropriate revisions to the case-mix payment adjustments for CY 2016, in the CY 2016 ESRD PPS proposed rule (80 FR 37816) we proposed to update the BSA Medicare national average from 1.87 m^2 to 1.90 m^2 for CY 2016 to reflect the new Medicare ESRD national average BSA. The average is based on an analysis of the patient height and weight information reported on ESRD facility claims in CY 2013. We note that this average is an increase of 1.6 percent over the Medicare ESRD national average BSA of 1.87 m^2 used to compute the payment adjustment when the ESRD PPS was implemented in CY 2011.

Based upon the regression analysis for CY 2016 using the DuBois and DuBois formula for computing a patient's BSA and the updated Medicare national average BSA of 1.90 m^2, we proposed that the BSA payment adjustment would be 1.032 and the BSA payment adjustment would be based on the following formula:

$1.032^{((\text{Patient's BSA} - 1.90)/0.1)}$.

Low-Body Mass Index (BMI)

The basic case-mix adjusted composite rate payment system in effect from CYs 2005 through 2010 and the current ESRD PPS include a payment adjustment for low BMI. In order to be consistent with other Department of Health and Human Services components (that is, Centers for Disease Control and Prevention and National Institutes for Health), we defined low BMI as less than 18.5 kg/m^2. The regression indicated that patients who are underweight consume more resources than other patients. The current payment adjustment for low BMI under the ESRD PPS is 1.025.

Based on the regression analysis conducted for the proposed rule, we continue to find low BMI to be a strong predictor of cost variation among ESRD patients. We proposed a payment adjustment of 1.017, reflective of the regression analysis based upon CY 2012 and 2013 Medicare cost report and claims data.

The comments we received and our responses are presented below.

Comment: MedPAC pointed out that in considering both body size adjustments, for patients with low BMI, the ESRD PPS applies an adjustment factor that increases payment by 2.5 percent; however, those patients tend to have BSA values less than the average, for which the ESRD applies an adjustment factor that decreases payment. They expressed concern that CMS has not stated exactly how each variable is incorporated in the regression models and that the proposed adjustment factors do not accurately account for the inherent correlation between patient BMI and BSA. They point out that the BSA is empirically estimated only in the facility-based regression, while the low-BMI adjustment factor is estimated only in the patient-based regression. MedPAC contends that this specification does not address the joint effect of patient BSA and BMI in each regression.

MedPAC conducted a regression in which they defined the dependent variable as the average cost per treatment (for services included in the PPS payment bundle), included the same independent and control variables as the CMS model and specified a set of BSA variables to take into account the distribution of BSA values at each facility. This approach allowed them to assess the joint effect of low BMI and BSA. With this specification, they found that the low BMI factor is statistically significant and increases payment by enough to offset reductions in payment resulting from low BSA. To account for this correlation, MedPAC recommended that CMS refine the low BMI and BSA adjustment to reflect the factors' joint effect on facility costs. One method they suggested could be to continue applying the same adjustment for BSA when patient BMI values are 18.5 kg/m^2 or greater, but for BMI values less than 18.5 kg/m^2, apply a single adjustment factor that takes into account the joint effect of patient BSA and low BMI. Their analysis suggests that a joint BSA and low BMI adjustment factor would be about 1.02 to 1.03.

Response: As we explained in the previous section, the BSA and low-BMI variables represent different characteristics that have individual effects on cost. In particular, BSA (which is a continuous variable that increases as the patient's body size rises) is empirically associated with higher composite rate costs. The low BMI categorical variable identifies particularly frail patients, that is, those with BMI less than 18.5 kg/m^2 and is empirically associated with higher separately billable costs because these very frail patients require more expensive drug therapies. Because of the continued importance of both body size adjustments to account for the costs associated with overweight and underweight patients, we appreciate the modeling that MedPAC conducted, which retains both body size adjusters.

The proposed example from MedPAC is not substantially different from the current model. The payment multipliers take account the joint effect of BSA and BMI: One effect for those with low BMI (BSA effect * 1.017) and one effect for those without a low BMI (BSA effect). Their proposal is essentially two continuous effects which start at differing cost averages (as indicated by the presence or absence of low BMI which moves the average costs up by 1.017). The ultimate effect is very similar to our model. We will, however, consider this approach for future refinement.

Comment: National dialysis organizations and two nursing associations also pointed out that a patient with a low BMI frequently has a negative BSA, eliminating the benefit of the low BMI adjustment for that patient. A national association of kidney patients and a nonprofit dialysis organization agreed and referred to an analysis that concluded that the BSA adjuster is canceling out the BMI adjuster in most cases for underweight patients. The commenters' healthcare professionals attest that both underweight and overweight patients require additional staff time devoted to their care and overweight patients may require the facility to provide additional equipment. To ensure that the patient level adjusters are achieving the intended policy purpose of protecting these seemingly more costly patients from adverse selection, the commenters recommend maintaining the current (2015) age adjuster, eliminating the BSA adjuster, and applying a BMI adjuster only for underweight patients, adding a BMI adjuster for overweight patients (using the National Institutes of Health definition) for 2016, and working with the kidney community to develop new data sources for patient characteristics from which appropriate age and weight adjusters could be calculated in future years.

Response: We agree with the commenters that both underweight and overweight patients require additional resources devoted to their care. Also, the commenters are correct that the BSA adjustment would be negative for frail patients and the low-BMI adjustment counteracts this effect. While BSA is negatively correlated with low BMI, the correlation is not perfect. The low BMI adjustment does not just counteract the negative BSA adjustment. Rather, where a patient's BMI is under the threshold

of 18.5 kg/m², the combined effect of the low BMI and the BSA adjustment is an increase in payment for frail patients. We discuss the interaction between the BSA and low BMI variable in section II.B.1.

The suggestion that we retain elements from the current model, such as the current (2015) age adjusters, and adopt new measures based on the updated regression using ESRD PPS data, would not be appropriate. We must either retain the current case-mix adjustments in their entirety or adopt the proposed adjustment multipliers derived from the updated regression analysis; adopting a mixture of adjustments from different regression analyses would remove the empirical basis of the payment system. We are unable to consider a new BMI-based adjustor for overweight patients for implementation in CY 2016. We would first need to consider the various options suggested, decide on a methodology, run the regression analysis using the new adjustor, and obtain public comments. We will consider this approach for future refinement of the ESRD PPS.

Comment: A large dialysis organization suggested that CMS eliminate the BSA adjuster for 2016 and beyond. They recommend that CMS retain the BMI adjuster, but only with modifications so that it addresses both underweight and overweight patients. This could be achieved by establishing a threshold for overweight patients and using the existing dollars from the BSA adjuster pool to fund this new category. Alternatively, the organization provides a proposal on how to possibly combine the two adjusters into one based on BMI and ensure differential reimbursement for overweight and underweight patients. The alternative BMI adjuster would be based on the number of cubed deviations (deviation equal to two points in BMI) from the average dialysis patient BMI (~28.9 kg/m²). The LDO's proposed formula for a patient's BMI adjuster would be as follows:

$$\text{BMI adjustor} = 1.00007^{([\text{Patient BMI} - \text{Average BMI}]/2)^3}$$

Using this method, the LDO stated that the new BMI adjuster would maintain budget neutrality and, most importantly from its point of view, align more closely with the policy objectives than using the proposed threshold methodology. The commenter indicated that applying a BMI threshold is somewhat arbitrary and would result in drastically different reimbursement for patients who have very similar BMI (that is, a patient with BMI of 25 kg/m² would receive incremental reimbursement but a patient with BMI of 24.9 kg/m² would not). The commenter noted that presumably, costs and reimbursement should be quite similar for patients with numerically close BMI scores.

Response: We selected BSA and low BMI because they improve the model's ability to predict costs compared to using BMI or weight alone. We provided the BSA adjustment as a proxy for time on the dialysis machine and additional staff or supply resources for overweight patients. As noted in the previous response, we are unable to implement a high-BMI adjustment in CY 2016. With regard to the suggestion that we fund this new BMI-based adjustment and achieve budget neutrality by using the payments currently paid through the BSA adjustment, we would instead need to estimate a regression model with the new specification and determine the budget-neutrality factor needed to fund the adjuster.

In the current model, the BSA adjustment is unique as it is standardized to the mean, and therefore does not contribute to the overall budget-neutrality factor (that is, the multiplier is 1.0 on average, with larger patients adjusted upward and smaller patients adjusted downward. For all other case-mix adjusters, the value of 1.0 is assigned to the lowest cost group, and all adjustments are upward, which is what necessitates the budget-neutrality factor. Alternative approaches to accounting for body size might be explored for future payment years. If such an alternative retained the property of the BSA adjustment in which the average multiplier is standardized to 1.0, it would not require a budget-neutrality adjustment.

We do not understand the example provided to illustrate the commenter's view that applying a BMI threshold is somewhat arbitrary and would result in drastically different reimbursement for patients who have very similar BMI. In the example, a patient with a BMI of 24.9 kg/m² is compared to a patient with a BMI of 25 kg/m². As the BMI adjuster is not applied unless the patient has a BMI of 18.5 kg/m², we note that neither of the patients in the example would receive the low-BMI adjustment.

Comment: An organization of nonprofit SDOs asked CMS to address the potential interaction of the two related but separate adjustment factors addressing body size. They suggested that we create a floor below which a negative BSA adjustment would not apply to avoid interaction with the BMI adjustment. Specifically, they recommended that the BSA adjustor not be applied to a patient with a BMI of less than 18.5 kg/m.

Response: The regression model assumes that the low-BMI adjuster is tempered by the BSA adjustment. As a result, if we were to adopt the commenter's suggestion to remove the interaction between the two variables by creating a floor for the BSA at the low-BMI level, the proposed low-BMI adjuster would be too high and would need to be recalculated.

Comment: An MDO noted that the payment multiplier for low-BMI dropped from 1.025 to 1.017 and asked why we feel the adjustment warrants a decrease and what the regression showed that prompted us to propose this change. They pointed out that patients with a low BMI need more care, so they should continue to receive the higher adjustment amount.

Response: The updated regression analysis is based on ESRD PPS data and reflects reduced utilization of ESAs and other renal dialysis service drugs, biologicals, and laboratory testing. The decrease in separately billable services resulted in a decrease in the weight applied to the separately billable multipliers in the calculation of the payment multipliers. The actual multiplier for low BMI rose slightly from 1.078 in the analysis for CY 2011 to 1.090 in the analysis for the CY 2016. Therefore, the decline in the overall payment multiplier for low BMI noted by the commenter arose entirely from the lower overall weight attached to SB services given their substantial decline following the implementation of the expanded bundled payment system.

Comment: A professional association requested that CMS clearly define the methodology for calculating BMI and BSA. For example, for PD patients, they asked whether the weight measured when the patient has an empty peritoneal cavity or a full peritoneal cavity. The association notes this is particularly relevant for those patients who have high volume dwells at all times, as the full volume could theoretically be subtracted from the weight to derive a value that more closely approximates body weight. Similarly, for hemodialysis, the association requests that CMS define when weight is assessed in regard to dialysis schedule.

Response: The Medicare Claims Processing Manual (Pub. 100–4, Chapter 8, section 50.3) states that the weight of the patient should be measured after the last dialysis session of the month and is reported in kilograms. Additionally, the Medicare Benefit Policy Manual (Pub. 100–02, Chapter 11, section 60.A.3) states that although height and weight

are taken at intervals throughout any given month of dialysis treatment, the measurements for the purpose of payment must be taken as follows: The dry weight of the patient is measured and recorded in kilograms immediately following the last dialysis session of the month. For PD patients, dry weight occurs when the patient has an empty peritoneal cavity, which can be obtained by subtracting the remaining volume from the patient's weight. We will consider the commenter's suggestion in future revisions to those manuals.

After consideration of the public comments, effective January 1, 2016, we are adopting the proposed payment multipliers for the BSA (1.032) and low-BMI (1.017) payment adjustments which are included in Table 4 of this final rule. We are also updating the average Medicare ESRD patient national average weight used in the BSA formula to 1.90 m^2.

(3) Comorbidities

Section 1881(b)(14)(D)(i) of the Act requires that the ESRD PPS include a payment adjustment based on case-mix that may take into account patient comorbidities. In our CY 2011 ESRD PPS proposed and final rules (74 FR 49952 through 49961 and 75 FR 49094 through 49108, respectively), we described the proposed and finalized comorbidity payment adjustors under the ESRD PPS. Our analysis found that certain comorbidity categories are predictors of variation in costs for ESRD patients and, as such, we proposed the following comorbidity categories as payment adjustors: Cardiac arrest; pericarditis; alcohol or drug dependence; positive HIV status or AIDS; gastrointestinal tract bleeding; cancer (excluding non-melanoma skin cancer); septicemia/shock; bacterial pneumonia and other pneumonias/opportunistic infections; monoclonal gammopathy; myelodysplastic syndrome; hereditary hemolytic or sickle cell anemias; and hepatitis B (74 FR 49954).

While all of the proposed comorbidity categories demonstrated a statistically significant relationship with additional cost in the payment model, the various issues and concerns raised in the public comments regarding the proposed categories caused us to do further evaluations. Specifically, we created exclusion criteria that assisted in deciding which categories would be recognized for the payment adjustment. As discussed in the CY 2011 ESRD PPS final rule (75 FR 49095) we further evaluated the comorbidity categories with regard to—(1) inability to create accurate clinical definitions; (2) potential for adverse incentives regarding care; and (3) potential for ESRD facilities to directly influence the prevalence of the comorbidity either by altering dialysis care or diagnostic testing patterns, or liberalizing the diagnostic criteria. As a result of this evaluation, we finalized 6 comorbid patient conditions eligible for additional payment under the ESRD PPS (75 FR 49099 through 49100): pericarditis, bacterial pneumonia, gastrointestinal tract bleeding with hemorrhage, hereditary hemolytic or sickle cell anemias, myelodysplastic syndrome, and monoclonal gammopathy.

Many stakeholders have criticized the comorbidity payment adjustments available under the ESRD PPS. Through industry public comments and stakeholder meetings we have become aware of the perceived documentation burden placed upon facilities in their effort to obtain discharge information from hospitals or other providers or diagnostic information from physicians and other practitioners necessary to substantiate the comorbidity on the facility claim form. Public comments have suggested that we remove all comorbidity payment adjustments from the payment system and return any allocated monies to the base rate. Other commenters have indicated that patient privacy laws have also limited the ability of facilities to obtain the diagnosis documentation necessary in order to append the appropriate International Classification of Diseases code on the claim form.

Acute Comorbidity Categories

There are three acute comorbidity categories (pericarditis, bacterial pneumonia, and gastrointestinal tract bleeding with hemorrhage) finalized in the CY 2011 ESRD PPS final rule (75 FR 49100) due to predicted short term increased facility costs when furnishing dialysis services. Specifically, the costs were identified with increased utilization of ESAs and other services. The payment adjustments are applied to the ESRD PPS base rate for 4 months following an appropriate diagnosis reported on the facility monthly claim. In the CY 2011 ESRD PPS final rule, we finalized payment variables as indicated in Table 2 below.

TABLE 2—ACUTE COMORBIDITY CATEGORIES RECOGNIZED FOR A PAYMENT ADJUSTMENT UNDER THE ESRD PPS

Acute comorbidity category	CY 2011 Payment multiplier	CY 2016 Payment multiplier
Pericarditis	1.114	1.040
Bacterial Pneumonia	1.135	
Gastrointestinal Tract Bleeding w/Hemorrhage	1.183	1.082

In the CY 2016 ESRD PPS proposed rule (80 FR 37817), we explain that analysis of CYs 2012 and 2013 claims data for the regression analysis continues to demonstrate significant facility resources when furnishing dialysis services to ESRD patients with these acute comorbidities. However, in accordance with section 632(c) of ATRA and in response to stakeholders' public comments and requests for the elimination of all of the comorbid payment adjustments, we have compared the frequency of how often these conditions were indicated on the facility monthly bill type with how often a corroborating claim in another Medicare setting is identified in a 4-month look back period. We were unable to corroborate the diagnoses of bacterial pneumonia on ESRD facility claims with the presence of a diagnosis on claims from other Medicare settings, leading us to the conclusion that this comorbidity is significantly under-reported by ESRD facilities.

In order for the bacterial pneumonia comorbid payment adjustment to apply, we require three specific sources of documentation: an X-ray, a sputum culture, and a provider assessment. Since 2011, facilities have expressed concern regarding these documentation requirements. Specifically, facilities cite a documentation burden in that they are unable to obtain hospital or other discharge information for the patients in their care, and are therefore unable to submit the diagnosis on the claim form necessary to receive a payment adjustment. In addition, stakeholders have indicated that our requirements are

out of step with the assessments used by many physicians and Medicare providers to make the diagnosis. For example, many providers will diagnose bacterial pneumonia simply by patient assessment and would not consider the X-ray or the sputum culture necessary to their diagnosis.

Because in the opinion of stakeholders, the ESRD PPS comorbidity payment adjustments often go unpaid, facilities have encouraged CMS to eliminate these adjustments through the authority granted in section 632(c) of ATRA. However, we find that all of the acute comorbid payment adjustors continue to be strong predictors of cost variation among ESRD patients based on the updated regression analysis. Accordingly, we continue to believe it is appropriate to apply a comorbidity payment adjustment for the acute comorbidities of pericarditis and gastrointestinal tract bleeding with hemorrhage. However, in consideration of stakeholder concerns about the burden associated with meeting the documentation requirements for bacterial pneumonia, we proposed to eliminate the case-mix payment adjustment for the comorbidity category of bacterial pneumonia beginning in CY 2016. Based upon the regression analysis of CY 2012 through 2013 Medicare claims and cost report data, where comorbidities are measured only on ESRD facility claims, the proposed payment adjustment for pericarditis would be 1.040 and the adjustment for gastrointestinal tract bleeding with hemorrhage would be 1.082.

Chronic Comorbidity Categories

There are three chronic comorbidity categories (hereditary hemolytic and sickle cell anemias, myelodysplastic syndrome, and monoclonal gammopathy), which were finalized as payment adjustors in the CY 2011 ESRD PPS final rule (75 FR 49100) due to a demonstrated prediction of increased facility costs when furnishing dialysis services. In addition, these conditions have demonstrated a persistent effect on costs over time; that is, once the condition is diagnosed for a patient, the condition is likely to persist. For this reason, the payment adjustments are paid continuously when an appropriate diagnosis code is reported on the facility's monthly claim. In the CY 2011 ESRD PPS final rule, we finalized payment variables as indicated in Table 3 below for chronic comorbidities, effective January 1, 2011.

TABLE 3—CHRONIC COMORBIDITY CATEGORIES RECOGNIZED FOR A PAYMENT ADJUSTMENT UNDER THE ESRD PPS

Chronic comorbidity category	CY 2011 payment multiplier	CY 2016 payment multiplier
Hereditary Hemolytic or Sickle Cell Anemias	1.072	1.192
Myelodysplastic Syndrome	1.099	1.095
Monoclonal Gammopathy	1.024	

In the CY 2016 ESRD PPS proposed rule (80 FR 37818), we explain that analysis of CY 2012 through 2013 claims and cost report data for the purposes of regression analysis has continued to demonstrate that significant facility resources are used when furnishing dialysis services to ESRD patients with these chronic comorbidities. However, in accordance with section 632(c) of ATRA and in response to stakeholders' public comments and requests for the elimination of all of the comorbid payment adjustments, we compared the frequency of how often these conditions were reported on the facility monthly bills with how often a corroborating claim is reported in another Medicare setting in a 12-month look back period. This analysis demonstrated significant differences in the reporting of monoclonal gammopathy by ESRD facilities and in other treatment settings.

In order for the monoclonal gammopathy comorbidity payment adjustment to apply, Medicare requires a positive serum test and a bone marrow biopsy test. We believe that billing inconsistency may result from the variation in diagnostic assessment for the condition. We believe that some facilities may report the diagnosis based upon only the positive serum test, and forgo the bone marrow biopsy, while other facilities may view the bone marrow biopsy as excessive for what is often an asymptomatic condition and forgo the payment adjustment altogether.

CMS has historically required the bone marrow biopsy for confirmation of a diagnosis of monoclonal gammopathy because often it is a laboratory-defined disorder, where the disease has no symptoms but where the patient is identified to be at considerable risk for the development of multiple myeloma. Because many ESRD patients suffer from anemic conditions due to their dialysis, they can test false positive for monoclonal gammopathy. We considered modifying our documentation policies for requiring the bone marrow biopsy when making the payment adjustment. However, we are concerned that we will be unable to confirm the diagnosis without a bone marrow test.

Based on the regression analysis conducted using CY 2012 and 2013 ESRD PPS claims and cost report data, we find that all of the chronic comorbid payment adjustors continue to be strong predictors of cost variation among ESRD patients and accordingly, we proposed to continue to make a payment adjustment for the chronic comorbid conditions of hereditary hemolytic and sickle cell anemias and myelodysplastic syndrome. However, in consideration of stakeholders' concerns about the excessive burden of meeting the documentation requirements for monoclonal gammopathy, due to variation in patient assessment, we proposed to eliminate the case-mix payment adjustment for the comorbid condition of monoclonal gammopathy beginning in CY 2016. Based upon the regression analysis of CY 2012 through 2013 ESRD facility claims and cost report data, the updated payment adjustment for hereditary hemolytic and sickle cell anemias would be 1.192 and for myelodysplastic syndrome the payment adjustment would be 1.095.

The comments we received and our responses are set forth below:

Comment: MedPAC expressed support for the proposal to eliminate bacterial pneumonia and monoclonal gammopathy as payment adjustments under the ESRD PPS. In addition, they recommend that CMS consider removing all comorbidity payment adjustments because they may result in undue burden on patients required to undergo additional diagnostic procedures, are poorly identified on dialysis claims, and reflect only differences in the cost of separately

billable services. They note that to the extent that these conditions result in high costs, these costs are addressed through the outlier policy.

Many national dialysis organizations representing small, medium and large dialysis organizations, nursing associations, and a professional association also supported our proposal to eliminate two of the comorbidity category adjustments. Several organizations pointed out that comorbidities such as these are not generally diagnosed in the ESRD facility or by physicians associated with the facility. Regardless of the fact that comorbid conditions may be indicative of higher patient ESA utilization and thus higher ESRD treatment costs, the commenters claim that the policy rationale of these adjusters is not being met. Due to the burdensome requirements related to documentation and diagnosis coding requirements needed for clinical comorbidity adjustments, dialysis providers are not able to receive this adjustment for many patients' comorbidities because of incomplete patient medical histories, as well as a lack of availability of specialty and primary care health records.

The national dialysis organizations agreed with MedPAC's assertion that the outlier payment policy is sufficient for the purpose of reimbursing dialysis providers for treating patients with pericarditis, gastrointestinal bleeding, hereditary, hemolytic, or sickle cell anemia, and myelodysplastic syndrome. For these reasons, they recommended that we eliminate all of the remaining comorbidity adjustments and rely upon the outlier policy to fine-tune the payment to facilities caring for the small number of beneficiaries who may incur higher costs due to comorbidities.

Several other organizations representing mostly SDOs and independent ESRD facilities commented that the frequency of reporting of codes for the comorbidity adjustments remains significantly below CMS's estimates because dialysis facilities continue to face challenges in getting the required documentation in order to report specific diagnosis codes and obtain the comorbidity payment adjustments. The organization states that there are many dialysis patients who have GI bleeding and are even hospitalized multiple times without there ever being a confirmed diagnosis by their GI specialist. Yet, the dialysis unit bears the burden of the higher costs associated with this condition. An MDO commented that a more fair and reasonable change to the comorbid condition payment multipliers would be to either change or decrease the documentation requirements for bacterial pneumonia and monoclonal gammopathy so more providers qualify for the adjustments. Another organization of SDOs agreed, noting similar problems with obtaining the required documentation for the GI bleeding with hemorrhage comorbidity and suggested that CMS exercise its discretion to further limit, if not withdraw completely, the comorbidities included in the current case-mix adjustments.

Response: In response to the suggestion that we change or decrease the documentation requirements for bacterial pneumonia and monoclonal gammopathy rather than remove the comorbidity categories, we believe removing these comorbidities is more appropriate. As we stated in the CY 2016 ESRD PPS proposed rule (80 FR 37817), in order for the bacterial pneumonia comorbid payment adjustment to apply, we require three specific sources of documentation: An x-ray, a sputum culture, and a provider assessment. Due to the variation in diagnostic assessment, we find that the condition is underreported on facility claims and that we are unable to confirm a positive diagnosis without the additional burden of documenting an X-ray or sputum culture.

For monoclonal gammopathy, in the CY 2016 ESRD PPS proposed rule (80 FR 37818), we stated that CMS has historically required documentation of a bone marrow biopsy to confirm a diagnosis of monoclonal gammopathy because often it is a laboratory-defined disorder, where the disease has no symptoms but where the patient is identified to be at considerable risk for the development of multiple myeloma. Because many ESRD patients suffer from anemic conditions due to their dialysis, they can test false positive for monoclonal gammopathy. We considered modifying our documentation policies for requiring the bone marrow biopsy when making the payment adjustment. However, we are concerned that we will be unable to confirm the diagnosis without a bone marrow test. Based on our concern regarding the variation in diagnostic testing, we proposed to delete monoclonal gammopathy as a payment adjustment. Because of the patient and facility burden associated with these conditions, we continue to believe it is appropriate to delete bacterial pneumonia and monoclonal gammopathy as payment adjustments under the ESRD PPS.

With regard to the problems organizations described in obtaining the documentation needed to report a comorbidity, we did not intend that ESRD facilities would actually order additional tests or procedures in order to document a comorbidity. Rather, our assumption was that the patient's nephrologist or primary care physician would be aware if their patient had any of the two chronic conditions and would provide the documentation. If there is nothing in the medical record, then the facility would be unable to claim a comorbidity adjustment for that patient and would have to seek payment through the outlier mechanism.

With regard to the acute comorbidity categories, we do not understand how ESRD facilities are unable to obtain confirmatory documentation for most ESRD patients with gastrointestinal tract bleeding with hemorrhage and pericarditis. Considering the ICD–10–CM codes that are available for reporting these conditions under the ESRD PPS, we believe in most cases these patients would be evaluated and treated in an acute care setting such as an emergency room or hospital and, as a result, it should not be burdensome or difficult for ESRD facilities to obtain the documentation. We believe that if a patient has one of the comorbidities, a physician must have done a clinical work up to make the diagnosis. Diagnoses are based on clinical signs and symptoms as well as diagnostic tests and these findings are included in the medical record.

Obtaining the medical documentation necessary to obtain payments for the comorbidities we proposed to retain should not be complicated or burdensome; and is important for care coordination purposes. Once the patient signs a medical release form (which could be done while the patient is in the dialysis facility) and it is faxed to either the hospital or the physician office, the records should be released. In situations where the patient's medical record is incomplete so the ESRD facility is unable to obtain the documentation needed to report the comorbidity diagnosis, we would expect the facility to include the cost for all outlier-eligible services on the claim and qualify for an outlier payment when the cost exceeds the outlier fixed dollar loss threshold. This approach supports access to dialysis for high cost patients. We will continue to monitor the extent to which the comorbidities are reported for future refinement.

MedPAC also made a comment regarding the comorbidity payment adjustment reflecting only differences in the cost of separately billable services. We note that accurate multipliers for uncommon conditions could not be derived from the facility-level model. If

we were to use the facility-level model and link those comorbidities with composite rate costs in addition to drugs, we would not have been able to detect that with any reasonable level of statistical precision. Therefore, we believe that it is appropriate to derive the comorbidity payment adjustments from the separately billable model.

With regard to the comments concerning the comorbidity payment adjustment not being paid out as we had anticipated in CY 2011, we note that prior to the implementation of the expanded bundle in 2011, comorbidities were rarely reported on dialysis claims. Therefore, the 2011 model predicted the prevalence of comorbidity adjusters using Medicare claims from other settings (except for laboratory claims). That predicted prevalence was used in the calculation of the case-mix adjustment budget-neutrality factor. Actual reporting on dialysis claims during the first year of the expanded bundle fell short of the levels expected based on diagnoses reported on claims from other care settings. It was not known at that time whether such underreporting would become persistent or if reporting would rise as providers became more familiar with the requirements of the new payment system. Since there are now several years of data that have demonstrated continued reporting below expected levels, we have come to agree with the comment that the comorbidities are less frequently documented on ESRD facility claims compared to the reporting on claims in other care settings. However, rather than eliminate the comorbidities as several commenters suggest, we have revised the predicted prevalence of comorbidity adjusters in our calculation of the refinement budget-neutrality adjustment factor to be based on actual reporting in the dialysis setting. Specifically, the 2016 model refinement is based on comorbidities identified for payment on dialysis claims only, that is, for this final rule we have reset our assumptions to reflect the actual prevalence of the comorbidity adjusters in the ESRD population. The budget-neutrality adjustment accounts for the elimination of monoclonal gammopathy and bacterial pneumonia as well as the actual prevalence of reported comorbidities on dialysis claims.

We anticipate going forward, the reduction in the base rate to fund comorbidity adjusters will be in balance with actual payments made for those adjusters. This is demonstrated by comparing the amount of the estimate of the direct reduction in the base rate due to the comorbidities provided in column 3 of Table 4, which shows the value for the CY 2011 model, with that in column 7 of Table 4, which shows the value for the CY 2016 model. Specifically, if all other variables are held constant, in the CY 2011 model 0.8 percent of the base rate was held to fund the comorbidity payment adjustments, whereas in the CY 2016 model 0.1 percent of the base rate will be held to fund the comorbidity payment adjustments.

We agree with MedPAC and other commenters that in the absence of case-mix adjusters for comorbidities, it would be more likely that facilities would receive outlier payments. However, this would only partially compensate facilities for the higher costs associated with the comorbidity. If the costs for these patients are higher but do not reach the outlier fixed dollar loss threshold, facilities would not receive outlier compensation. Even if the outlier threshold is met, facilities would only receive compensation for costs above the threshold. Therefore, we believe it is appropriate to retain four of the comorbidity payment adjusters in order to ensure that ESRD facilities receive additional payment for these costly patients and preserve access to care for patients with these conditions.

Comment: A large health plan requested that we reconsider our proposal to delete the comorbidity category of bacterial pneumonia. They pointed out that when a patient has bacterial pneumonia, additional costs are incurred by ESRD facilities for antibiotic treatment, pulmonary destabilization secondary to pneumonia, and tests such as X-rays for fluid buildup. The plan encouraged us to provide adequate reimbursement for this condition.

Response: Under the ESRD PPS, ESRD facilities are responsible only for furnishing renal dialysis services, which are defined in 42 CFR 413.171. Payment adjustments are made to ESRD facilities for comorbidities to reflect the increased utilization and cost of ESAs and other renal dialysis services drugs and laboratory testing furnished to patients with these comorbidities. The ESRD facilities are not responsible for the costs related to treatment of the comorbidity, such as antibiotic treatment and x-rays in the case of bacterial pneumonia, but rather only for the cost of the renal dialysis services they are required to furnish.

Comment: An MDO disagreed with the decrease in the payment multipliers for pericarditis (from 1.114 to 1.040) and gastrointestinal bleeding (from 1.183 to 1.082) and stated that removing an entire payment multiplier for a comorbid condition and also decreasing the others will be detrimental to providers. They noted that the other comorbidity payment multipliers for hereditary hemolytic or sickle cell anemia (from 1.072 to 1.192) and mylodysplastic syndrome (from 1.099 to 1.095) appear to be acceptable.

Response: The reduction in the payment multipliers for many of the adjustments under the ESRD PPS is due to the decrease in utilization of renal dialysis service drugs and biologicals, especially ESAs reflected in the updated regression analysis. In light of the reduction in utilization and facility costs for renal dialysis service drugs and biologicals, the new payment multipliers reflect facility cost on average and therefore should not be detrimental to ESRD facilities.

After consideration of public comments, effective January 1, 2016, we are adopting the proposed comorbidity category payment multipliers provided in Table 2 for the acute comorbidity categories of pericarditis and gastrointestinal tract bleeding with hemorrhage and Table 3 for the chronic comorbidity categories of hereditary hemolytic or sickle cell anemias and myelodysplastic syndrome of the CY 2016 ESRD PPS proposed rule (80 FR 37817 and 80 FR 37818, respectively) as final. The multipliersare presented below in Table 4. We are also finalizing removal of monoclonal gammopathy and bacterial pneumonia from the comorbidities eligible for payment adjustments.

(4) Onset of Dialysis

Section 1881(b)(14)(D)(i) of the Act required the ESRD PPS to include a payment adjustment based on case-mix that may take into account a patient's length of time on dialysis. For the CY 2011 ESRD PPS final rule (75 FR 49090), we analyzed the length of time beneficiaries have been receiving dialysis and found that patients who are in their first 4 months of dialysis have higher costs and noted that there was a drop in the separately billable payment amounts after the first 4 months of dialysis. Based upon this analysis, we proposed and finalized the definition of onset of dialysis as beginning on the first date of reported dialysis on CMS Form 2728 through the first 4 months a patient is receiving dialysis. We finalized a 1.510 onset of dialysis payment adjustment for both home and in-facility patients (75 FR 49092). In addition, we acknowledged that there may be patients whose first 4 months of dialysis occur when they are in the coordination of benefits period and not yet eligible for the Medicare ESRD benefit. We explained that in these circumstances, no onset of dialysis

adjustment would be made (75 FR 49090).

Most commenters supported inclusion of an onset of dialysis patient-level adjustment and noted that the higher costs for new patients are due to the stabilization of the health status of the patient and dialysis training. Because the Medicare onset of dialysis payment adjustment reflects the costs associated with all of the renal dialysis services furnished to a Medicare beneficiary in the first 4 months of dialysis, additional payment adjustments are not made for comorbidities or training during the months in which the onset of dialysis payment adjustment is made. We discussed and finalized this payment adjustment in the CY 2011 ESRD PPS final rule (75 FR 49092 through 49094).

Based on the regression analysis conducted for the refinement, we found that the onset of dialysis continues to be a strong predictor of cost variation among ESRD patients and proposed an updated payment adjustment of 1.327.

The comments we received and our responses are set forth below:

Comment: One large health plan expressed concern about the drop in the onset of dialysis payment multiplier. They stated that new patients require a significant amount of resources as many have been hospitalized, and require frequent medication adjustments, higher dosing regimens of ESAs and more frequent lab testing. They recommend we review the analysis to ensure adequate payment is made for new patients. Another organization noted that CMS did not offer a rationale for the reduction of the multiplier for onset of dialysis. They are concerned that the practical effect of the proposal to lower the multiplier would be lower payments for the treatment of patients in this critical stage. They requested that we reevaluate this proposal and make its policy rationales for any changes available to the dialysis community.

Response: The proposed onset of dialysis payment adjustment was derived from a regression analysis of CY 2012 and 2013 claims and cost report data and reflects decreased use of renal dialysis service drugs and laboratory testing, particularly ESAs. We believe it is important for Medicare payment to reflect the changes in practice that have occurred with implementation of the bundled payment system in 2011 and believe that the proposed revised adjuster value captures the cost of the onset of dialysis under the ESRD PPS.

Comment: A dialysis supply manufacturer was also concerned about the reduction in the onset of dialysis payment adjustment and the unintended effect it could have on training for home hemodialysis (HHD). This is because when an ESRD facility is receiving the onset of dialysis adjustment for a patient, training add-on payments are not made. Thus, the commenter is concerned that a reduced onset of dialysis adjustment factor may lead to less HHD training.

Response: For HHD, most of the reported training treatments occur after the first four months when the onset of dialysis adjustment no longer applies; 83 percent of Medicare HHD training treatments occur after the first four months (based on 2014 claims). Data in the June 2014 claims indicates 492 patient months where the patient qualified for the onset of dialysis adjustment and was in HHD training. That number would equate to approximately 50 to 100 patients in a year and represents 0.24 percent of all patients months qualifying for the onset of dialysis adjustment (that total is 202,687).

It appears to be common for patients do in-facility hemodialysis first (with the facility receiving the onset of dialysis adjustment), and then the patient receives HHD training (with the facility receiving the training adjustment). The reasons for this could be legitimate, such as a patient not receiving modality education before starting, so the decision to do HHD is made after starting in-facility. Sometimes patients decide to do HHD before needing dialysis, but when they start, they are too uremic to do training, and so a period of in-facility hemodialysis to attain stability comes first, and then training follows. Less legitimate would be if facilities are focused on the payments rather than the patient. Then they simply have the patient do in-center HD first, collect the onset adjustment, and then train them on HHD. They get both payments. In the scenario where a patient both identifies that they want to do HHD, and are well enough to start off right away with training, we believe they have had better than average pre-ESRD care and/or are healthier than the average patient starting HHD, and so may not have the same costs during the four-month onset of dialysis period as the average onset patient (for example, starting with an AVF, better anemia management, etc).

After consideration of the public comments, effective January 1, 2016, we are adopting the proposed payment multiplier of 1.327 for the onset of dialysis adjustment. The finalized payment adjustment is in Table 4 below.

In summary, we are finalizing the adult case-mix payment adjustments as provided in Table 4 below. In addition, this table also reflects the facility-level payment adjustments addressed in the next section.

TABLE 4—CY 2016 ADULT CASE-MIX AND FACILITY-LEVEL PAYMENT ADJUSTMENTS

Variable	EB multipliers for CY2011	Estimate of the direct reduction in base rate due to this factor, for CY2011 (%)	CR multipliers for CY2016	SB multipliers for CY2016	EB multipliers for CY2016	Estimate of the direct reduction in base rate due to this factor, for CY2016 (%)
Age:						
18–44	1.171	.....	1.308	1.044	1.257	
45–59	1.013	.....	1.084	1.000	1.068	
60–69	1.000	3.1	1.086	1.005	1.070	8.400
70–79	1.011	.....	1.000	1.000	1.000	
80+	1.016	.....	1.145	0.961	1.109	
Body surface area (per 0.1 m^2)	1.020	0.0	1.039	1.000	1.032	0.000
Underweight (BMI <18.5)	1.025	0.1	1.000	1.090	1.017	0.058
Time since onset of renal dialysis <4 months	1.510	2.5	1.307	1.409	1.327	1.307
Facility low volume status	1.189	0.3	1.368	0.955	1.239	0.410
Comorbidities:						
Pericarditis (acute)	1.114	0.0	1.000	1.209	1.040	0.005

TABLE 4—CY 2016 ADULT CASE-MIX AND FACILITY-LEVEL PAYMENT ADJUSTMENTS—Continued

Variable	EB multipliers for CY2011	Estimate of the direct reduction in base rate due to this factor, for CY2011 (%)	CR multipliers for CY2016	SB multipliers for CY2016	EB multipliers for CY2016	Estimate of the direct reduction in base rate due to this factor, for CY2016 (%)
Gastro-intestinal tract bleeding (acute)	1.183	0.2	1.000	1.426	1.082	0.040
Bacterial pneumonia (acute)	1.135	0.3				
Hereditary hemolytic or sickle cell anemia (chronic)	1.072	0.1	1.000	1.999	1.192	0.022
Myelodysplastic syndrome (chronic)	1.099	0.2	1.000	1.494	1.095	0.028
Monoclonal gammopathy (chronic)	1.024	0.0				
Rural			1.015	0.978	1.008	0.118

d. Refinement of Facility-Level Adjustments

i. Low-Volume Payment Adjustment

Section 1881(b)(14)(D)(iii) of the Act requires a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent. As required by this provision, the ESRD PPS provides a facility-level payment adjustment to ESRD facilities that meet the definition of a low-volume facility. A background discussion on the low-volume payment adjustment (LVPA) and a proposal regarding the LVPA eligibility criteria is provided below.

The current amount of the LVPA is 18.9 percent. In the CY 2011 ESRD PPS final rule (75 FR 49125), we indicated that this increase to the base rate is an appropriate adjustment that will encourage small facilities to continue to provide access to care. With regard to the magnitude of the payment adjustment for low-volume facilities, we stated that it is more appropriate to use the regression-driven adjustment rather than the 10 percent minimum adjustment mentioned in the statute because it is based on empirical evidence and allows us to implement a payment adjustment that is a more accurate depiction of higher costs.

For the CY 2016 ESRD PPS proposed rule (80 FR 37819), we analyzed those ESRD facilities that met the definition of a low-volume facility as specified in 42 CFR 413.232(b) as part of the updated regression analysis. We found that the cost per treatment for these facilities is still high compared to other facilities. With regard to the magnitude of the payment adjustment for low-volume facilities, we continue to believe that it is appropriate to use the regression-driven adjustment because it is based on empirical evidence and allows us to implement a payment adjustment that is a more accurate depiction of higher costs. In the proposed rule, we stated that the regression analysis of CY 2012 and 2013 low-volume facility claims and cost report data indicated a payment multiplier of 1.239 percent. Accordingly, we proposed an updated LVPA adjustment factor of 23.9 percent for CY 2016 and future years.

ii. CY 2016 Proposals for the Low-Volume Payment Adjustment (LVPA)

(1) Background

As required by section 1881(b)(14)(D)(iii) of the Act, the ESRD PPS provides a facility-level payment adjustment of 18.9 percent to ESRD facilities that meet the definition of a low-volume facility. Under 42 CFR 413.232(b), a low-volume facility is an ESRD facility that, based on the documentation submitted pursuant to 42 CFR 413.232(h): (1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and (2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year. Under 42 CFR 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership and 25 road miles or less from the ESRD facility in question. Our regulation at 42 CFR 413.232(d) exempts facilities that were in existence and Medicare-certified prior to January 1, 2011 from the 25-mile geographic proximity criterion, thereby grandfathering them into the LVPA.

For purposes of determining eligibility for the LVPA, ''treatments'' means total hemodialysis (HD) equivalent treatments (Medicare and non-Medicare). For peritoneal dialysis (PD) patients, one week of PD is considered equivalent to 3 HD treatments. In the CY 2012 ESRD PPS final rule (76 FR 70236), we clarified that we base eligibility on the three years preceding the payment year and those years are based on cost reporting periods. We further clarified that the ESRD facility's cost reports for the periods ending in the three years preceding the payment year must report costs for 12-consecutive months (76 FR 70237).

In the CY 2015 ESRD PPS final rule (79 FR 66152 through 66153), we clarified that hospital-based ESRD facilities' eligibility for the LVPA should be determined at an individual facility level and their total treatment counts should not be aggregated with other ESRD facilities that are affiliated with the hospital unless the affiliated facilities are commonly owned and within 25 miles of each other. Therefore, the MAC can consider other supporting data in addition to the total treatments reported in each of the 12-consecutive month cost reports, such as the individual facility's total treatment counts, to verify the number of treatments that were furnished by the individual hospital-based facility that is seeking the adjustment.

In the CY 2015 ESRD PPS final rule (79 FR 66153), with regards to the cost reporting periods used for eligibility, we clarified that when there is a change of

ownership that does not result in a new Medicare Provider Transaction Access Number but creates two non-standard cost reporting periods (that is, periods that are shorter or longer than 12 months) the MAC is either to add the two non-standard cost reporting periods together where combined they would equal 12-consecutive months or prorate the data when they would exceed 12-consecutive months to determine the total treatments furnished for a full 12-month cost reporting period as if there had not been a CHOW.

In order to receive the LVPA under the ESRD PPS, an ESRD facility must submit a written attestation statement to its MAC confirming that it meets all of the requirements specified at 42 CFR 413.232 and qualifies as a low-volume ESRD facility. In the CY 2012 ESRD PPS final rule (76 FR 70236), we finalized a yearly November 1 deadline for attestation submission and we revised the regulation at § 413.232(f) to reflect this date. We noted that this timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria. In the CY 2015 ESRD PPS final rule (79 FR 66153 through 66154), we amended § 413.232(f) to accommodate the timing of the policy clarifications finalized for that rule. Specifically, we extended the deadline for the CY 2015 LVPA attestations until December 31, 2014 to allow ESRD facilities time to assess their eligibility based on the policy clarifications for prior years under the ESRD PPS and apply for the LVPA for CY 2015. Further information regarding the administration of the LVPA is provided in the Medicare Benefit Policy Manual, CMS Pub. 100–02, Chapter 11, section 60.B.1.

2) The United States Government Accountability Office Study on the LVPA

In the CY 2015 ESRD PPS final rule (79 FR 66151 through 66152), we discussed the study that the United States Government Accountability Office (the GAO) conducted on the LVPA. We also provided a summary of the GAO's main findings and recommendations. We stated that the GAO found that many of the facilities eligible for the LVPA were located near other facilities, indicating that they may not have been necessary to ensure sufficient access to dialysis care. They also identified certain facilities with relatively low volume that were not eligible for the LVPA, but had above-average costs and appeared to be necessary for ensuring access to care. Lastly, the GAO stated the design of the LVPA provides facilities with an adverse incentive to restrict their service provision to avoid reaching the 4,000 treatment threshold.

In the conclusion of their study, the GAO provided the Congress with the following recommendations: (1) To more effectively target facilities necessary for ensuring access to care, the Administrator of CMS should consider restricting the LVPA to low-volume facilities that are isolated; (2) To reduce the incentive for facilities to restrict their service provision to avoid reaching the LVPA treatment threshold, the Administrator of CMS should consider revisions such as changing the LVPA to a tiered adjustment; (3) To ensure that future LVPA payments are made only to eligible facilities and to rectify past overpayments, the Administrator of CMS should take the following four actions: (i) require Medicare contractors to promptly recoup 2011 LVPA payments that were made in error; (ii) investigate any errors that contributed to eligible facilities not consistently receiving the 2011 LVPA and ensure that such errors are corrected; (iii) take steps to ensure that CMS regulations and guidance regarding the LVPA are clear, timely, and effectively disseminated to both dialysis facilities and Medicare contractors; and (iv) improve the timeliness and efficacy of CMS's monitoring regarding the extent to which Medicare contractors are determining LVPA eligibility correctly and promptly re-determining eligibility when all necessary data become available.

As we explained in the CY 2015 ESRD PPS final rule (79 FR 66152), we concurred with the need to ensure that the LVPA is targeted effectively at low-volume high-cost facilities in areas where beneficiaries may lack dialysis care options. We also agreed to take action to ensure appropriate payment is made in the following ways: (1) evaluating our policy guidance and contractor instructions to ensure appropriate application of the LVPA; (2) using multiple methods of communication to MACs and ESRD facilities to deliver clear and timely guidance; and (3) improving our monitoring of MACs and considering measures that can provide specific expectations.

3) Addressing GAO's Recommendations

As discussed above, in the CY 2015 ESRD PPS final rule (79 FR 66152), we made two clarifications of the LVPA eligibility criteria that were responsive to stakeholder concerns and GAO's concern that the LVPA should effectively target low-volume, high-cost facilities. However, we explained that we did not make changes to the adjustment factor or significant changes to the eligibility criteria because of the interaction of the LVPA with other payment adjustments under the ESRD PPS. Instead, we stated that in accordance with section 632(c) of ATRA, for CY 2016 we would assess facility-level adjustments and address necessary LVPA policy changes when we would use updated data in a regression analysis similar to the analysis that is discussed in the CY 2011 ESRD PPS final rule (75 FR 49083).

For CY 2016, because we are refining the ESRD PPS, we reviewed the LVPA eligibility criteria and proposed changes that we believe address the GAO recommendation to effectively target the LVPA to ESRD facilities necessary for ensuring access to care.

4) Elimination of the Grandfathering Provision

In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49119), we expressed concern about potential misuse of the LVPA. Specifically, our concern was that the LVPA could incentivize dialysis companies to establish small ESRD facilities in close geographic proximity to other ESRD facilities in order to obtain the LVPA, thereby leading to unnecessary inefficiencies. To address this concern, we finalized that for the purposes of determining the number of treatments under the definition of a low-volume facility, the number of treatments considered furnished by the ESRD facility would be equal to the aggregate number of treatments furnished by the ESRD facility and other ESRD facilities that are both: (i) Under common ownership with; and (ii) 25 road miles or less from the ESRD facility in question. However, we finalized the grandfathering of those commonly owned ESRD facilities that were certified for Medicare participation on or before December 31, 2010, thereby exempting them from the geographic proximity restriction.

We established the grandfathering policy in 2011 in an effort to support low-volume facilities and avoid disruptions in access to essential renal dialysis services while the ESRD PPS was being implemented. However, now that the ESRD PPS transition is over and facilities have adjusted to the ESRD PPS payments and incentives, we believe it is appropriate to eliminate the grandfathering provision. Because we are doing a refinement of the payment adjustments under the ESRD PPS for CY 2016, the timing is appropriate for eliminating the grandfathering policy so that this change can be assessed along

with other proposed changes to the ESRD PPS resulting from the regression analysis.

In the CY 2016 ESRD PPS proposed rule (80 FR 37820), we proposed that for the purposes of determining the number of treatments under the definition of a low-volume facility, beginning in CY 2016, the number of treatments considered furnished by any ESRD facility regardless of when it came into existence and was Medicare certified would be equal to the aggregate number of treatments actually furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both: (i) Under common ownership with; and (ii) 5 road miles or less from the ESRD facility in question. The proposed 5 road mile geographic proximity mileage criterion is discussed below. We proposed to amend the regulation text by removing paragraph (d) in 42 CFR 413.232 to reflect that the geographic proximity provision described in paragraph (c) and discussed below is applicable to any ESRD facility that is Medicare certified to furnish outpatient maintenance dialysis. We solicited comment on the proposed change to remove the grandfathering provision by deleting paragraph (d) from our regulation at 42 CFR 413.232.

5) Geographic Proximity Mileage Criterion

In GAO's report, they stated that the LVPA did not effectively target low-volume facilities that had high costs and appeared necessary for ensuring access to care. The GAO stated that nearly 30 percent of LVPA-eligible facilities were located within 1 mile of another facility in 2011, and about 54 percent were within 5 miles, which indicated to them that these facilities might not have been necessary for ensuring access to care. Furthermore, the GAO indicated that in many cases, the LVPA-eligible facilities were located near high-volume facilities. The GAO explained in the report that providers that furnish a low volume of services may incur higher costs of care because they cannot achieve the economies of scale that are possible for larger providers. They also stated that low-volume providers in areas where other care options are limited may warrant higher payments because, if Medicare's payment methods did not account for these providers' higher cost of care, beneficiary access to care could be reduced if these providers were unable to continue operating. They further explained that in contrast, low-volume providers that are in close proximity to other providers may not warrant an adjustment because beneficiaries have other care options nearby.

We agree with the GAO's assertion that it may not be appropriate to provide additional payment to an ESRD facility that is located in close proximity to another ESRD facility when the facilities are commonly owned. The purpose of the LVPA is to recognize high cost, low-volume facilities that are unable to achieve the economies of scale that are possible for larger providers such as large dialysis organizations (LDO) and medium dialysis organizations (MDO). In addition, we note that under the current LVPA eligibility criteria, approximately half of low-volume facilities are LDO and MDO facilities that have the support of their parent companies in controlling their cost of care.

In the proposed rule (80 FR 37821), we explained that we analyzed the ESRD facilities receiving payment under Medicare for furnishing renal dialysis services in CY 2013 for purposes of simulating different eligibility scenarios for the LVPA. The CY 2013 claims and cost report data was the best data available. We stated in the proposed rule that the CY 2014 cost reports would be available later in the year. For this final rule we still do not have complete cost report data for CY 2014 and therefore could not update our analysis.

For the analysis we simulated the MAC's verification process in order to determine LVPA eligibility. Our analysis considered the treatment counts on cost reporting periods ending in 2010 through 2012, the corresponding CY 2013 LVPA eligibility criteria defined at 42 CFR 413.232, and the location of low-volume facilities to assess the impact of various potential geographic proximity criteria. Because we used the CY 2013 claims and attestations, our analysis did not match the facilities currently receiving the LVPA because we were unable to analyze 2014 cost reports of LVPA facilities at that time. However, this analysis allowed us to test various geographic proximity mileage amounts to determine whether facilities eligible for the LVPA in 2013 would continue to be eligible for the LVPA as well as allowing us to determine the existence of any other ESRD facilities in those areas.

Initially, we applied the low-volume eligibility criteria (without grandfathering) and the current 25 road mile criterion and categorized facilities by urban/rural location, type of ownership, and other factors, and determined that out of the total of 434 low-volume facilities, 38 percent of LVPA facilities would lose low-volume status, including 19 percent in rural areas. For those determined to meet the LVPA criteria, we also assessed the extent to which there were other ESRD facilities (in the same chain or other chain), located within 5 road miles and 10 road miles from the LVPA facilities. Based on our concern that too many rural and independent facilities would lose low-volume status if we used the 25 road mile geographic proximity criterion, we then analyzed 1 road mile, 5 road miles, 10 road miles, 15 road miles, and 20 road miles in order to determine a mileage criterion that protected rural facilities while supporting access to renal dialysis services in rural areas. We believe that ESRD facilities located in rural areas are necessary for access to care and we would not want to limit LVPA eligibility for rural providers.

Based on this analysis, we proposed to reduce the geographic proximity criterion from 25 road miles to 5 road miles because our analysis showed that no rural facilities would lose LVPA eligibility due to the proposed 5 road mile geographic proximity criterion. This policy would discourage ESRD organizations from inefficiently operating two ESRD facilities within close proximity of each other. This policy would also allow ESRD facilities that are commonly owned to be considered individually when they are more than 5 miles from another facility that is under common ownership. We proposed to amend the regulation text by revising paragraph (c)(2) in 42 CFR 413.232 to reflect the change in the mileage for the geographic proximity provision. We solicited comments on the proposed change to 42 CFR 413.232(c)(2). We note that our analysis indicated that approximately 30 facilities that are part of LDOs and MDOs would lose the LVPA due to the 5 mile proximity change and the elimination of grandfathering, which caused many facilities to exceed 4000 treatments. For this reason, we stated that we considered whether a transition would be appropriate and requested public comments.

iii. Geographic Payment Adjustment for ESRD Facilities Located in Rural Areas

1) Background

Section 1881(b)(14)(D)(iv)(III) of the Act provides that the ESRD PPS may include such payment adjustments as the Secretary determines appropriate, such as a payment adjustment for ESRD facilities located in rural areas. Accordingly, in the CY 2011 ESRD PPS proposed rule we analyzed rural status as part of the regression analysis used to

develop the payment adjustments under the ESRD PPS. In the CY 2011 ESRD PPS proposed rule (74 FR 49978), we discuss our analysis of rural status as part of the regression analysis and explained that to decrease distortion among independent variables, rural facilities were considered control variables rather than payment variables. We indicated that based on our impact analysis, rural facilities would be adequately reimbursed under the proposed ESRD PPS. Therefore, we did not propose a facility-level adjustment based on rural location and we invited public comments on our proposal.

In the CY 2011 ESRD PPS final rule (75 FR 49125 through 49126), we addressed commenters' concerns regarding not having a facility-level adjustment based on rural location. Some of the commenters provided an explanation of the unique situations that exist for rural areas and the associated costs. Specifically, the commenters identified several factors that contribute to higher costs including higher recruitment costs to secure qualified staff; a limited ability to offset costs through economies of scale; and decreased negotiating power in contractual arrangements for medications, laboratory services, and equipment maintenance. The commenters were concerned about a negative impact on beneficiary access to care that may result from insufficient payment to cover these costs. In addition, the commenters further noted that rural ESRD facilities have lower revenues because they serve a smaller volume of patients of which a larger proportion are indigent and lack insurance, and a smaller proportion have higher paying private insurance.

In response to the comments discussed above, we indicated that according to our impact analysis for the CY 2011 ESRD PPS final rule, rural facilities, as a group, were projected to receive less of a reduction in payments as a result of implementation of the ESRD PPS than urban facilities and many other subgroups of ESRD facilities and, therefore, we did not implement a facility-level payment adjustment that is based on rural location. However, we stated our intention to monitor how rural ESRD facilities fared under the ESRD PPS and consider other options if access to renal dialysis services in rural areas is compromised under the ESRD PPS.

2) Determining a Facility-Level Payment Adjustment for ESRD Facilities Located in Rural Areas Beginning in CY 2016

Since implementing the ESRD PPS, we have heard from industry stakeholders that rural facilities continue to have the unique difficulties described above when furnishing renal dialysis services that cause low to negative Medicare margins. Because we are committed to promoting beneficiary access to renal dialysis services, especially in rural areas, we analyzed rural location as a payment variable in the regression analysis conducted for the CY 2016 ESRD PPS proposed rule.

Including rural areas as a payment variable in the regression analysis showed that this facility characteristic was a significant predictor of higher costs among ESRD facilities and we proposed a payment multiplier of 1.008. The adjustment would be applied to the ESRD PPS base rate for all ESRD facilities that are located in a rural area. In the CY 2011 ESRD PPS final rule (75 FR 49126), we finalized the definition of rural areas in 42 CFR 413.231(b)(2) as any area outside an urban area. We defined urban area in 42 CFR 413.231(b)(1) as a Metropolitan Statistical Area or a Metropolitan division (in the case where Metropolitan Statistical Area is divided into Metropolitan Divisions). We proposed to add a new section to our regulations at § 413.233 to provide that the base rate will be adjusted for facilities that are located in rural areas, as defined in § 413.231(b)(2).

The rural facility adjustment would also apply in situations where a facility is eligible to receive the low-volume payment adjustment. In other words, a facility could be eligible to receive both the rural and low-volume payment adjustments. Low-volume and rural areas are two independent variables in the regression analysis. The low-volume variable measures costs facilities incur as a result of furnishing a small number of treatments whereas the rural area variable measures the costs associated with locality. The regression analysis indicated that being in a rural area—regardless of treatments furnished—explains an increase in costs for furnishing dialysis compared to urban areas. Since low-volume and rural areas are independent variables in the regression, we believe that a low-volume facility located in a rural area would be eligible for both adjustments. We believe that while the magnitude of the payment multiplier is small, rural facilities would still benefit from the adjustment. Therefore, we proposed a 1.008 facility-level payment multiplier under the ESRD PPS for rural areas and solicited comment on this proposal.

(3) Further Investigation Into Targeting High-Cost Rural ESRD Facilities

Section 3127 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) required that the Medicare Payment Advisory Commission (MedPAC) study and report to Congress on: (1) Adjustments in payments to providers of services and suppliers that furnish items and services in rural areas; (2) access by Medicare beneficiaries' to items and services in rural areas; (3) the adequacy of payments to providers of services and suppliers that furnish items and services in rural areas; and (4) the quality of care furnished in rural areas. The report required by section 3127(b) of the Affordable Care Act was published in the MedPAC June 2012 Report to Congress: Medicare and the Health Care Delivery System (hereinafter referred to as June 2012 Report to Congress), which is available at *http://www.medpac.gov/documents/reports/jun12_entirereport.pdf.* In addition to the findings presented on each of the four topics, this report presented a set of principles designed to guide expectations and policies with respect to rural access, quality, and payments for all sectors, which can be used to guide Medicare payment policy. For purposes of the proposed rule, we were most interested in the principles of payment adequacy and special payments to rural providers.

In the June 2012 Report to Congress, MedPAC explained that providers in rural areas often have a low volume of patients and in some cases, this lack of scale increases costs and puts the provider at risk of closure. MedPAC stated that to maintain access in these cases, Medicare may need to make higher payments to low-volume providers that cannot achieve the economies of scale available to urban providers. However, they explained that low volume alone is not a sufficient measure to assess whether higher payments are warranted and that Medicare should not pay higher rates to two competing low-volume providers in close proximity. They stated that these payments may deter small neighboring providers from consolidating care in one facility, which results in poorly targeted payments and can contribute to poorer outcomes for the types of care where there is a volume-outcome relationship. MedPAC further explained that to target special payments when warranted, Medicare should direct these payments to providers that are uniquely essential for maintaining access to care in a given community. The payments need to be

structured in a way that encourages efficient delivery of healthcare services.

MedPAC presented three principles guiding special payments that will allow beneficiaries' needs to be met efficiently: (1) Payments should be targeted toward low-volume isolated providers—that is, providers that have low patient volume and are at a distance from other providers. Distance is required because supporting two neighboring providers who both struggle with low-volume can discourage mergers that could lead to lower cost and higher quality care; (2) the magnitude of special rural payment adjustments should be empirically justified, that is, the payments should increase to the extent that factors beyond the providers' control increase their costs; and (3) rural payment adjustments should be designed in ways that encourage cost control on the part of providers.

We were interested in the information that MedPAC provided in their report regarding services furnished to Medicare beneficiaries in rural areas. We believe that the adjustment that we proposed, which we arrived at through a regression analysis, is consistent with principle two above, which states that the magnitude of special rural payment adjustments should be empirically justified. We considered alternatives to deriving the adjustment from the regression analysis in an effort to increase the value of the adjustment. For example, we could establish a larger adjustment independent of the regression and offset it by a reduction to the base rate. We also considered analyzing different subsets of rural areas and designating those areas as the payment variable in our model. Because we were able to determine through the regression analysis that rural location is a predictor of cost variation among ESRD facilities, we are planning to analyze the facilities that are located in rural areas to see if there are subsets of rural providers that experience higher costs. We are also planning to explore potential policies to target areas that are isolated or identify where there is a need for health care services, such as, for example, the frontier counties (that is, counties with a population density of six or fewer people per square mile) and we would also consider the use of Health Professional Shortage Area (HPSA) designations managed by the Health Resources and Services Administration (HRSA). Information regarding HPSAs can be found on the HRSA Web site: *http://bhpr.hrsa.gov/shortage/hpsas/designationcriteria/*.

We believe that this type of analysis would be consistent with the June 2012 Report to Congress's principle that special payments should target the low-volume facilities that are isolated. We solicited comments on establishing a larger payment adjustment outside of the regression analysis. We noted that such an adjustment would need to be offset by a further reduction to the base rate. For example, we could compare the average cost per treatment reported on the cost report of ESRD facilities located in rural areas with ESRD facilities located in urban areas and develop a methodology to derive the magnitude of the adjustment. In addition, we solicited comments on targeting subsets of rural areas for purposes of using those facilities located in those areas for analysis as payment variables in the regression analysis used to develop the payment multipliers for the refinement for CY 2016.

As most of the commenters combined their views on the low-volume and rural adjustments, we present these comments and responses followed by specific comments and responses on each adjustment.

Comment: MedPAC expressed concern that neither the low-volume adjustment nor the rural adjustment targets facilities that are critical to beneficiary access. They recommend a single adjustment that targets low-volume isolated providers in place of the two separate adjustments we proposed. In addition, MedPAC expressed support for the GAO recommendation that we avoid giving facilities an incentive to limit services to avoid reaching the low volume treatment threshold (the so-called cliff effect). They suggest that a payment approach that decreases the payment adjustment as facility volume increases might reduce this incentive.

Several dialysis organizations and a national patient organization recommended that we rely upon a two-tiered low-volume adjuster policy with the current LVPA (as modified by CMS in the proposed rule) as tier 1. Rather than adopting a rural adjuster and using the dollars allocated for the rural adjuster, CMS could create a second low-volume adjustment. The tier-2 adjustment would apply to rural facilities that furnish between 4001–6000 treatments per year. Other professional associations expressed support for this tiered approach.

One organization suggested that CMS consider using a tiered LVPA that would pay higher for rural facilities that are also low-volume, while still applying an adjustment (although of a lesser amount) to low-volume facilities that may be in closer proximity to other commonly owned dialysis facilities. Since rural status for facilities may be associated with higher costs independent of the number of treatments they provide, CMS should consider adding a tier of the LVPA that would provide a payment adjustment for a higher range of treatments delivered for facilities with a rural designation. A simplified example of this tiered approach may look like the following:

1. Rural + <4,000 treatments 75 percent of the LVPA adjuster value
2. Rural + 4,001 − 6,000 treatments 50 percent of the LVPA adjuster value
3. <4,000 treatments 25 percent of the LVPA adjuster value

They noted that the geographic proximity rules may still be necessary with this approach, which could serve as an interim solution until such a time that CMS is able to conduct further analysis to better identify facilities that are geographically isolated.

Another organization suggested that CMS expand the low-volume adjuster to include a second tier for facility volume rather than applying a rural adjuster that is less representative of real facility costs. Their proposed second tier, medium volume classification would include those facilities administering between 4,001 and 7,000 treatments annually. They indicated that these facilities, in aggregate, have lower margins than rural facilities. Combining the dollars from the proposed rural adjuster and the increase in the current low-volume adjuster would result in a new adjuster of approximately 1.025 for all treatments at medium volume facilities. They indicate that reimbursement based on volume is superior to reimbursement based on geography due to proper alignment with the costs of care.

Response: We appreciate the useful suggestions for refining the LVPA from the commenters. However, significant changes to the eligibility criteria would need to be proposed to provide the opportunity for public input. We believe that the proposed policy changes represent improvement in the targeting of the payment adjustment. We will certainly consider these suggestions for future refinement as our analyses of low-volume and rural ESRD facilities continue.

Comment: An LDO organization commented that, in their experience, the primary challenge facing rural facilities is access to more patients and that most LVPA facilities are rural. However, rural facilities with a high volume of patients may be financially viable. In their view, rural and low-volume are not necessarily independent variables.

Another LDO commented that the proposed rural adjustment is inappropriate because it would be applied to all facilities at the same rate regardless of need. In their experience operating numerous rural facilities, they note that size is the driving factor in total facility cost rather than geographic location of the facility. Their analysis showed that high-volume rural facilities performed similarly to urban facilities with comparable data.

Response: As we explained above, low volume and rural areas are two independent variables in the regression analysis. The low-volume variable measures costs facilities incur as a result of furnishing a small number of treatments whereas the rural area variable measures the costs associated with locality. Consistent with the comment from the LDO, CMS' analysis found that low volume is associated with higher cost for both urban and rural facilities. CMS analysis also found that being in a rural area, regardless of the number of treatments furnished, explains an increase in costs for furnishing dialysis compared to urban areas. With regard to the commenter's impression that LVPA facilities are mostly rural, we note that in our analysis of CY 2014 claims data for the 419 facilities receiving the LVPA, the distribution is 227 urban and 192 rural.

Comment: An organization representing small and medium dialysis facilities and a large health plan expressed support for the update to the LVPA adjustment and appreciated our efforts to address the inherently high cost of low volume and rural facilities. They noted that while some facilities would lose the adjustment under the proposed changes, many of the facilities gaining the adjustment are independent, hospital-based, or part of a small dialysis organization. They believe this is an appropriate targeting of the LVPA and agree with the proposed changes.

A patient group also expressed support for the proposed changes to the LVPA and the proposed rural adjustment because they believe these adjustments will maintain payment levels at roughly their current levels. They also described the current lack of access to dialysis services in International Falls, Minnesota. While they indicate that resources have been found to fund startup costs, the commenter was disheartened that the Medicare payment apparently does not suffice to attract a for-profit LDO, as those organizations have greater access to capital and economy of scale in purchasing and other overhead costs. The commenters stated that CMS must remain vigilant to ensure that Medicare payments are sufficient to support the nationwide kidney care infrastructure that Congress intended Medicare coverage of ESRD to foster.

An organization representing small and medium dialysis facilities applauds CMS for proposing a rural adjustment. Although they agree with MedPAC that low-volume ESRD facilities that are necessary to maintain beneficiary access to care should receive enhanced payment, they disagree with MedPAC's recommendation to remove the rural adjustment. They noted several issues that create special circumstances for rural facilities, including increased salary and benefit costs and the costs associated with water quality issues and serving the needs of patients in remote areas.

Response: We thank these commenters for their support of the LVPA changes and the rural adjustment. With regard to the point that CMS must ensure that Medicare payments are sufficient to support the nationwide kidney care infrastructure, we believe the ESRD PPS is based on a sound and stable methodology, that the base rate covers dialysis treatment costs on average and that the outlier policy provides additional payment and ensures access for high-cost patients.

Comment: An organization representing small and medium dialysis facilities recommended that we make the rural adjustment an add-on payment rather than a multiplier of the base rate to allow rural facilities to realize the true value of the adjuster, and not subject them to a lower adjustment due to the effects of the rural wage index on the base rate.

Response: The model we have developed and implemented for the ESRD PPS in 2011 is multiplicative and as a result, an additive adjuster cannot be directly estimated from the model. That is, the regression was set up to produce multiplicative factors and as a result cannot produce an additive adjustment for one variable. However, if the extra resources required by patients receiving a case-mix adjustment partially involve labor, it is not clear why a multiplicative adjustment would not be appropriate because the added labor effort incurred by facilities in lower wage areas would also be paid at the lower wage. The rationale for the additive training adjuster in 2011 was that training treatments are such a small share of the total that a reliable adjuster could not be estimated from the model and, therefore, external assumptions about training costs were used to derive the additive adjustment. However, the rural multiplier can and should be estimated from the model, and serves to account for factors increasing costs in rural areas, after accounting for the wage index.

Comment: An organization urged CMS to establish a process for facilities to find resolution when their MACs have incorrect data. For example, some facilities may be eligible for the rural adjuster, but may not be receiving it due to incorrect data at the MAC. In these circumstances, the organization believes facilities should be able to appeal directly to CMS to ensure the MAC's data is correct and the facility is receiving the payment it is entitled to.

Response: We agree facilities should receive the low volume and the rural adjustments if they are eligible. The commenter did not provide specific examples of the types of data issues they were experiencing, however, we note that in order to receive the LVPA, MACs verify that the facilities' total treatments reported on their cost reports are under 4,000 and that the other LVPA criteria are met. Rural status is more straightforward to establish, but in both cases the MAC has to enter correct information in the Outpatient Provider Specific File (OPSF) so that the payment adjustments are applied to the claim. For this reason, we are planning to send out sub-regulatory guidance about the importance of keeping the information in the OPSF up-to-date and to address issues regarding incorrect data for the LVPA and rural adjustments.

Comment: A national patient organization also expressed concern that even with the proposed changes to the LVPA, the incentive still remains for facilities that have common ownership to maintain low-volume status while having two or more facilities serving in close proximity to a facility that has different ownership. For example, two facilities under common ownership could sit 10 miles from one another, but on either side of a facility that has different ownership causing all three facilities to potentially be low-volume facilities.

Response: The proposed LVPA adjustment is the first step toward improving the eligibility for payment. Our goal with this proposal was to minimize the impact on rural facilities. We have and are continuing to perform additional analysis in order to better target benefit distribution to those facilities serving the access needs of those in remote locations.

Comment: An SDO expressed support for the GAO's finding that too many closely located facilities are receiving the LVPA, stating that the focus needs to be placed on ensuring access to care. Consequently, they fully support the elimination of the grandfathering

provision. However, they recommend that we maintain the current geographic mileage proximity criterion of 25 road miles. Other organizations indicated that the rural payment adjustment should only be available to a clinic if there is not *any* outpatient dialysis clinic within five miles of the clinic.

Response: We appreciate the commenter's support of the removal of the grandfathering provision. The five mile geographic mileage proximity criterion was chosen for two reasons: (1) It eliminated the LVPA adjustment for those commonly-owned facilities with several facilities within a five mile radius with treatment counts just under 4000, and (2) it spared the impact on the rural facilities with geographic and topographical challenges. We plan on examining the impact of a future geographic facility adjustment applicable to all facilities, not just those that are commonly-owned.

Comment: An MDO also pointed out that under provider enrollment instructions a change of ownership (CHOW) typically occurs when a Medicare provider has been purchased or leased by another organization. The CHOW results in the transfer of the old owner's Medicare Identification Number and provider agreement (including any outstanding Medicare debt of the old owner) to the new owner. The regulatory citation for CHOWs can be found at 42 CFR 489.18. If the purchaser (or lessee) elects not to accept a transfer of the provider agreement, then the old agreement should be terminated and the purchaser or lessee is considered a new applicant. The commenter points out that the instructions fail to account for the rare instances when a provider does accept the agreement but ownership changed from hospital-based to independent, requiring a new provider number in the independent ESRD facility range of provider numbers. The commenter asked that CMS consider providers in these situations eligible for the LVPA for CY 2016 and future years and perhaps retroactively as well.

Response: We appreciate the commenter pointing out this scenario and we will examine options for addressing this concern.

Comment: An organization of nonprofit SDOs expressed support for the proposed change to the geographic proximity criterion and for the increase in the LVPA multiplier in recognition of the higher costs borne by low-volume facilities. However, they noted CMS could improve its proposal by providing that continuation of LVPA status be based on a three year rolling average, rather than the current one-year eligibility period, reducing the incentive to hold down the number of patients served in any given year for fear of exceeding the cap.

Response: We appreciate the commenter's support of the proposed change for the LVPA adjustment. We will consider the suggestion of a three-year rolling average for eligibility for the LVPA for future rulemaking.

Comment: Two nonprofit dialysis organizations expressed support for the rural adjustment and recommend the following conditions: (1) The rural adjustment should only be available for clinics that are not receiving the LVPA, that is, once a facility that benefits from the rural adjustment satisfies the LVPA criteria, it should have to choose which to forego; and (2) The rural adjustment should not be available to a clinic that provided more than 6000 treatments or 7000 treatments in the prior calendar year. An SDO also expressed support for the rural adjustment, but suggested that we consider limiting the rural adjustment to only those facilities located in a medically underserved area.

Response: As we explained above, the low-volume variable measures costs facilities incur as a result of furnishing a small number of treatments, whereas the rural area variable measures the costs associated with locality. The regression analysis indicated that being in a rural area, regardless of the number of treatments furnished, explains an increase in costs for furnishing dialysis compared to urban areas. Because low-volume and rural areas are independent variables in the regression, we believe that a low-volume facility located in a rural area would be eligible for both adjustments due to their high costs associated with both their location and their low patient volume.

Comment: A professional association also supports the rural adjustment, but notes that the proposed multiplier of 1.008 seems to be based on limited data. They expressed concern about the lack of accounting for SRR and other QIP measures. An SDO disagreed with our proposal to increase the LVPA multiplier from 18.9 percent to 23.9 percent and urged CMS to allocate the additional funds to the rural facility adjustment. They believe that based on the GAO study, it would appear that some LVPA funds could be allocated to funding the rural adjustment rather than further decreasing the base rate to fund the increase.

Response: The rural adjuster was based on the same data as the other adjusters. We are not aware of additional, national data that could be used to establish an adjuster. It is not clear why and how SRR and other QIP measures should be used as payment adjusters.

With respect to the commenters concern regarding the increase in the magnitude of the LVPA, CMS analyses found that both low volume facilities and rural facilities have higher costs than average, with the magnitudes reflected in the payment adjusters. A targeted reallocation of funds from facilities that could be eligible for the LVPA to rural facilities would not reflect estimates of the separate effect of rural location and low-volume on the cost of providing dialysis care.

Comment: In response to CMS requests for comments regarding developing a subset of rural providers to potentially establish a high payment adjustment, a professional association recommends that CMS postpone this measure until additional data can be generated. Another industry stakeholder recommended that we focus the rural adjuster on a smaller subset of rural facilities and provide them with a higher adjustment. They suggested we consider an approach based on population density that is similar to how CMS defines super rural.

Response: As we explain above, we are very interested in analyzing subsets of rural providers, such as facilities located in HPSA and frontier areas in order to better target facilities necessary to ensure access to care.

Comment: An MDO questioned how rural status is defined for the purpose of obtaining the rural adjustment. They asked if a facility would be considered rural where it is assigned a rural CBSA code—one with a 2 digit State CBSA—as opposed to the 5-digit urban CBSA code. An LDO indicated that the definition of rural, ''not in an urban area,'' is not suitable for use in a payment adjuster as it is too broad and does not address the specific issue.

Response: The rural adjustment would be paid to facilities that are not in a CBSA, that is, facilities that are assigned a two-digit State code. As we continue our analysis of subsets of rural providers, we will update the definition in 42 CFR 413.231.

Comment: Several professional associations recommended a transition period prior to implementation of the new geographic proximity criterion for the 30 facilities that will lose the LVPA. One association strongly recommends that CMS work closely with the parent networks to evaluate the impact of any closures on patient access to care.

Response: We do not anticipate that facilities will close because the LVPA will target facilities with truly high costs because of low patient volume. Analysis of the 2013 return code data shows that

3 facilities would be expected to receive the LVPA that were not previously grandfathered, and of these 3, none are expected to lose their LVPA adjustment. Of the 392 facilities that were grandfathered in 2013, 121(78 urban and 43 rural) are expected to lose the LVPA adjustment using the new LVPA eligibility criteria. Of the 43 rural facilities, all of them are expected to lose their LVPA eligibility because their treatment counts exceeded the 4000 treatment limit. None are expected to lose it due to the 5-mile geographic eligibility criterion. Of the 78 urban facilities that are expected to lose their LVPA adjustment, 45 have treatment counts that exceed the 4000 treatment limit, and 33 do not meet the 5-mile radius criterion.

Of note, there is at least one other dialysis facility within 5 miles for each one of the 33 dialysis facilities expected to lose their LVPA eligibility due to the 5-mile radius. Of the 33 facilities, 30 are LDOs and 27 out of the 33 facilities have multiple facilities within the 5 mile radius (two or more alternative facilities). Based on this analysis, we are not implementing a transition for facilities that will lose LVPA status at this time.

The LVPA adjustment was implemented to ensure facility availability for ESRD patients. Those facilities that are providing lower levels of treatments in a given year are supplemented with this adjustment to ensure their business survival and the continued availability of their services to the patients they serve. We believe we have made significant progress in targeting this population of dialysis facilities.

In summary, with respect to the LVPA, we are finalizing the proposed revisions to the eligibility criteria, that is, the removal of grandfathering and change in the geographic proximity criterion. Specifically, for the purposes of determining the number of treatments under the definition of a low-volume facility, beginning CY2016, the number of treatments considered furnished by any ESRD facility regardless of when it came into existence and was Medicare certified will be equal to the aggregate number of treatments actually furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both: (i) Under common ownership with; and (ii) 5 road miles or less from the ESRD facility in question. We are finalizing this provision by amending the regulation text by removing paragraph (d) in § 413.232, and revising the geographic proximity provision described in paragraph (c). ESRD facilities that meet the LVPA eligibility criteria at § 413.232 are eligible for the 23.9 percent increase to their ESRD PPS base rate as illustrated on Table 4.

We would like to note that we inadvertently failed to propose changes to the regulation text that pertains to the attestation deadline, in order to accommodate the timing of the policy changes finalized in this rule. Specifically, we are finalizing the extension of the attestation deadline for the CY 2016 LVPA attestations until December 31, 2015 to allow ESRD facilities time to assess their eligibility based on the policy changes to the LVPA for CY 2016 and, if appropriate, submit an attestation. Therefore, we are finalizing a revision to the newly redesignated § 413.232(e) to reflect this date.

In addition, we are finalizing the implementation of a rural payment adjustment of 0.8 percent. Specifically, this payment adjustment would be applied to the ESRD PPS base rate for all ESRD facilities that are located in a rural area. We are also finalizing the addition of § 413.233 to the regulation text to reflect this new adjustment.

e. Refinement of the Case-Mix Adjustments for Pediatric Patients

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made for renal dialysis services. This provision does not distinguish between services furnished to adult and pediatric patients. Therefore, we developed a methodology that used the ESRD PPS base rate for pediatric patients and finalized pediatric payment adjusters in our CY 2011 ESRD PPS final rule at 75 FR 49131 through 49134. Specifically, the methodology for calculating the pediatric payment adjusters reflects case-mix adjustments for age and modality. We noted in our CY 2011 ESRD PPS final rule that the payment adjustments applicable to composite rate services for pediatric patients were obtained from the facility level model of composite rate costs for patients less than 18 years of age and yielded a regression-based multiplier of 1.199. However, based upon public comments received expressing concern that the payment multiplier was inadequate for pediatric care, we revised our methodology and we finalized pediatric payment adjusters that reflected the overall difference in average payments per treatment between pediatric and adult dialysis patients for composite rate (CR) services and separately billable (SB) items in CY 2007 based on the 872 pediatric dialysis patients reflected in the data.

We indicated in the CY 2011 ESRD PPS final rule (75 FR 49131 through 49134), that the average CY 2007 Medicare Allowable Payment (MAP) for composite rate services for pediatric dialysis patients was $216.46, compared to $156.12 for adult patients. The difference in composite rate payment is reflected in the overall adjustment for pediatric patients as calculated using the variables of (1) age less than 13 years, or 13 through 17 years; (2) dialysis modality, that is, peritoneal dialysis (PD) or hemodialysis (HD). While the composite rate MAP for pediatric patients was higher than that for adult patients ($216.46 versus $156.12), the separately billable MAP was lower for pediatric patients ($48.09 versus $83.27), in CY 2007. There are fewer separately billable items in the pediatric model, largely because of the predominance of the PD modality for younger patients and the smaller body size of pediatric patients. The overall difference in the CY 2007 MAP between adult and pediatric dialysis patients was computed at 10.5 percent or $216.46 + $48.09 = $264.55 and $156.12 + $83.27 = $239.39. $264.55/$239.39 = 1.105.

For CY 2016, we explained in the CY 2016 ESRD PPS proposed rule (80 FR 37823), that for purposes of regression analysis, we did not propose any changes to the formula used to establish the pediatric payment multipliers and will continue to apply the computations of Mult*EB* = P * C * (W*CR* + W*SB* * Mult*SB*),where P is the ratio of the average MAP per session for pediatric patients to the average MAP per session for adult patients as shown below, C is the average payment multiplier for adult patients (1.1151), WCR (0.798) and WSB (0.202) are the proportion of MAP for CR and SB services, respectively, among pediatric patients, and MultSB represents the SB model multipliers. We are using updated values for P, C, WCR, and WSB along with the updated SB multipliers to calculate the updated EB multipliers. The overall difference in the CY 2013 MAP between adult and pediatric dialysis patients was computed at 8.2 percent (P = $283.42/ $ 261.91 = 1.082).

The regression analysis for a new pediatric payment model for Medicare pediatric ESRD patients for CY 2016 will use the same methodology that was used for the CY2011 ESRD PPS final rule, except for the use of more recent data years (2012 through 2013) and in the method of obtaining payment data. Specifically, we used the projected total expanded bundle MAP based on 2013 claims to calculate the ratio of pediatric

total MAP per session to adult total MAP per session. The projected MAP was calculated by pricing out utilization of SBs based on line items in the claims, rather than using actual payments from the claims as in the pre-2011 data. These adjustment factors reflected a proposed 8.21 percent increase to account for the overall difference in average payments per treatment for pediatric patients. For this final rule, we did not make changes to the pediatric model and are therefore finalizing the updated pediatric SB and EB multipliers as shown below in Table 5.

TABLE 5—CY 2016 PEDIATRIC CASE-MIX PAYMENT ADJUSTMENTS

Cell	Patient characteristics		CY 2016 final rule (based on 2012 and 2013 data)		
	Age	Modality	Population (%)	Separately billable multiplier	Expanded bundle payment multiplier
1	<13	PD	27.62	0.410	1.063
2	<13	HD	19.23	1.406	1.306
3	13–17	PD	20.19	0.569	1.102
4	13–17	HD	32.96	1.494	1.327

The comments we received and our responses are set forth below.

Comment: Two professional associations support the 8 percent increase in the pediatric case-mix adjusters, however, they expressed concern that it is inadequate to cover the actual cost of dialyzing children. They suggested that ongoing updates to the pediatric case-mix adjusters are warranted because without adequate reimbursement, it becomes difficult for facilities to maintain the specially trained staff to deliver quality care to pediatric patients. They state that our mutual goal should be to ensure that reimbursement is commensurate with actual cost so that pediatric facilities can continue to provide high quality care. They requested that CMS allow pediatric facilities to apply for an exception to the ESRD composite rate as it has in the past when a facility's cost reports showed that the actual cost per treatment was higher than the composite rate.

Response: We agree with the commenters that the ESRD pediatric patient population is unique because it represents a very small percentage of the overall dialysis population but has high utilization of renal dialysis services that are not as prevalent in the adult population. While our goal is to align reimbursement with costs, we continue to believe that our methodology described above will provide sufficient payment to ESRD facilities that treat pediatric ESRD patients as we discuss in the CY 2011 ESRD PPS final rule (75 FR 49128 through 49134). In addition, we have an existing outlier policy that can be utilized in the event the cost of a pediatric patient is excessive.

With regard to the request that we provide an exceptions process such as the one we provided under the composite rate payment system, under which Medicare paid a composite rate based on an individual facility's cost per treatment, we do not have the statutory authority to pay a different base rate from that applied to other ESRD facilities. Section 1881(b)(14)(A)(i) requires the Secretary to implement a payment system under which a single payment is made to a provider of services or renal dialysis facility for renal dialysis services in lieu of any other payment. We do not believe the statute gives us authority to utilize an exceptions process under the ESRD PPS.

As we indicated in the CY 2011 ESRD PPS final rule (75 FR 49178), pursuant to section 1881(b)(14) of the Act, we created an ESRD prospective payment system in lieu of payments under previous ESRD payment systems. Given that these payment exceptions pertained to the prior composite rate payment systems under sections 1881(b)(7) and(b)(12) of the Act, we do not believe that such exceptions would carry forward or be appropriate under the ESRD PPS. Because the ESRD PPS transition has concluded, no portion of the ESRD PPS payments are based on the composite rate, and as a result, it is not appropriate to resume composite rate exception payments.

Comment: One organization urged CMS to continue to reevaluate and regularly update the pediatric payment adjuster by utilizing the most recent data from Medicare cost reports and CROWNWeb.

Response: We agree it is important that the ESRD PPS payment adjustments are updated and refined so that the system reflects current clinical practice. Although we do not reevaluate and update the payment multipliers each year, we assess the impact of the changes we make to the ESRD PPS by simulating payments using the most recent year of ESRD facility claims and estimating the impact on facilities. For ESRD facilities that treat pediatric patients, we estimate the impact separately for facilities that treat less than 2 percent, between 2 and 19 percent, between 20 and 49 percent, and over 50 percent and publish the impacts in the annual ESRD PPS proposed and final rules.

f. The Home and Self-Dialysis Training Add-On Payment Adjustment

We received many comments from patients, patient advocacy groups, a dialysis supply manufacturer, national dialysis associations, and ESRD facilities concerning the adequacy of the home and self-dialysis training add-on payment adjustment. Although we did not make any proposals regarding the training add-on payment, we are addressing the commenters' concerns here.

Comment: Many commenters expressed concern about the adequacy of payment to ESRD facilities for training home and self-dialysis patients. Specifically, commenters expressed concern that the combination of inadequate payment and increasing costs to provide education for home therapies, especially home hemodialysis (HHD), could prevent patients from choosing home dialysis. Commenters asked us to consider changes to the training add-on payment adjustment, explaining that nursing time and quality training are essential to ensure patients are successful in taking care of themselves at home. The commenter asked CMS to ensure that the training add-on payment adjustment accurately reflects costs and sufficient staff time to thoroughly train patients and families, limiting the number of patients who return to receiving in-facility dialysis.

Two other patient advocacy organizations reiterated their support for

expanded patient access to home dialysis, pointing out that the percentage of patients using HHD remains low at just under 2 percent. The organizations noted that the upfront costs of beginning a home program may be one barrier to growth. They encouraged CMS to monitor patient access to home dialysis and ensure that the payment for home training covers the costs of the nursing time involved. They also expressed concern that any necessary increases to the training add-on payment adjustment should not come at the expense of funds from the ESRD PPS base rate, which those organizations believe are necessary to care for patients who chose to receive dialysis in-center.

A dialysis supply manufacturer provided an analysis indicating that adequate reimbursement of HHD training costs would require an additional $240 per treatment for each of the 25 training treatments allowed. They explained that 5 hours of one-on-one nursing time per HHD training treatment was necessary, rather than the 1.5 hours per treatment paid for by the current home dialysis training add-on payment adjustment. The $240 per treatment for each of the 25 training treatments allowed would compensate ESRD facilities for 5 hours of one-on-one nursing time per HHD training treatment.

A national dialysis association noted that their respective ESRD facilities do not observe an access barrier to HHD and indicated that they are not turning eligible patients or beneficiaries away from this modality. They stated that the ESRD PPS provides modality choice for beneficiaries that meet the clinical and practical requirements to dialyze at home. They noted that for many beneficiaries home dialysis is not a feasible option. The commenter noted that the beneficiary's home needs to be large enough to accommodate the equipment and supplies and be sufficiently sanitary to deliver dialysis that would otherwise be furnished under highly regulated conditions (that is, in-facility). In addition, while noting the unique challenges for both beneficiaries and providers, the commenter stated that some HHD machines are designed in such a way that the patient must dialyze more frequently than the three time per week schedule that has been the standard for achieving adequate therapy results. The commenter urged CMS and those in the kidney community to view home dialysis holistically and in the context of the broader ESRD PPS. The commenter suggested that if CMS wished to support home dialysis beneficiaries, then CMS should look at ways to restore funds to the ESRD PPS base rate for the care of all patients.

Response: We appreciate the commenters' suggestions regarding the evaluation of the home and self-dialysis training add-on payment adjustment. Access to care and the well-being of Medicare beneficiaries has always been our primary concern, and we agree that HHD is an important treatment option for patients that can appropriately use this modality. Additionally, we recognize the point raised by commenters that home dialysis is not a feasible option for all patients.

Home and self-dialysis training are programs that educate ESRD patients and/or other individuals to assist the patient in performing self-dialysis or home dialysis with little or no professional assistance. In the context of this response, since the commenters are specifically discussing training for hemodialysis to be completed by a patient and/or caregiver in the home, we refer to the add-on as the home dialysis training add-on adjustment. Under our current policy, ESRD facilities are entitled to bill a maximum of 25 training sessions per patient for HHD training. This provides ESRD facilities with payment for 37.5 total hours of training (that is, $1,881.00) for this dialysis modality through the home dialysis training add-on payment adjustment in addition to the training costs that are included in the ESRD PPS bundled payment rate. We believe this provides an adequate opportunity for training of ESRD beneficiaries. In fact, as we note below, the use of home dialysis has increased in the ESRD population since the implementation of the ESRD PPS.

While we have heard from the commenters that we should increase the home dialysis training add-on payment adjustment so that more ESRD patients can receive the benefit of HHD, we have also heard from LDOs that the current training add-on is sufficient. In addition to these differing viewpoints, we've also received information in public comments that indicate a wide variance in training times and the duration of training sessions. While we have heard different things from stakeholders about whether or not the home dialysis training add-on payment adjustment is adequate, we are not in a position this year to address the commenters' concerns. We are, however, committed to conducting further analysis of the home dialysis training add-on payment adjustment and will consider making appropriate changes to the adjustment in future rulemaking.

As described below, the regulatory history of the training add-on payment adjustment demonstrates recognition of the importance of preserving access to all modalities of dialysis treatment and a commitment to adequate payment for home hemodialysis. Beginning in the mid-1980s, we paid for home or self-dialysis training through a training add-on payment of $20 per treatment for 25 HHD treatments, $20 per treatment for 15 CCPD treatments, and $12 per treatment for 15 CAPD treatments. In the CY 2011 ESRD PPS proposed rule, we proposed that the cost for all home dialysis services would be included in the bundled payment (74 FR 49930). We noted that because we were proposing that training costs under the ESRD PPS would be treated no differently than any other overhead expense, an explicit adjustment to the bundled payment amount for HD and PD training expenditures would not be necessary (74 FR 49931). We also explained in the proposed rule that we were proposing modality neutral payments, because PD, the predominant modality for home dialysis at that time, is less costly than HD, and we believed that estimating a prospective rate that is higher for PD than it would otherwise be would encourage home dialysis for PD patients (74 FR 49967).

In the CY 2011 ESRD PPS final rule, we explained that we received comments encouraging us to consider utilizing an add-on payment adjustment to pay for the costs of home dialysis training. In response to those comments, we explained that although we were continuing to include training payments in computing the ESRD PPS base rate, we agreed with commenters that we should treat training as an adjustment under the ESRD PPS. Thus, we finalized the home dialysis training add-on payment adjustment of $33.44 per treatment as an additional payment made under the ESRD PPS when one-on-one home dialysis training is furnished by a nurse for either hemodialysis or peritoneal dialysis training and retraining (75 FR 49063). We chose to calculate a home dialysis training add-on payment adjustment based on one hour of nursing time because it was similar to the existing training add-on payments under the basic case-mix payment system (75 FR 49062). The amount we finalized for the adjustment—$33.44 per training treatment—was updated from the previous adjustment amount of $20 per hour and was based on the national average hourly wage for nurses from Bureau of Labor Statistics data updated to 2011 (75 FR 49063). We noted that

because nursing salaries differ greatly based on geographic location, we would adjust the training add-on payment by the geographic area wage index applicable to the ESRD facility. Based on the amount of the home dialysis training add-on payment adjustment that was finalized in 2011, facilities that furnished 25 HHD training treatments would receive around $500 in the form of home dialysis training add-on adjustment payments in addition to the dollars included in the base rate to account for training costs.

We clarified our policy on payment for home dialysis training again in the CY 2013 ESRD PPS final rule in which we stated that training costs are included in the ESRD PPS base rate, however, we also provide an add-on adjustment for each training treatment furnished by a Medicare-certified home dialysis training facility (77 FR 67468). As such, we explained that it is not the intent of the add-on treatment to reimburse a facility for all of the training costs furnished during training treatments. Rather, the single ESRD PPS base rate, all applicable case-mix and facility-level adjustments, as well as the add-on payment should be considered the Medicare payment for each training treatment and not the training add-on payment alone. We noted that the fact that the add-on payment for training accounts for one hour of training time per treatment is not intended to imply that it only takes one hour per training session to properly educate a beneficiary to perform home dialysis.

Then in the CY 2014 ESRD PPS final rule (78 FR 72183), we concluded in response to public comments that the training add-on, which represented 1 hour of nursing time, did not adequately represent the staff time required to ensure that a patient is able to perform home dialysis safely. We had received numerous comments on the home dialysis training add-on payment adjustment raising concerns about access to home dialysis and identifying training elements that were not contemplated in 2011, such as self-cannulation and certain aspects of operating an HHD machine. As a result, we recomputed the add-on based upon 1.5 hours of nursing time per training treatment, which amounted to a 50 percent payment increase of $16.72 per training treatment in addition to the training treatment costs included in the base rate. Therefore, the add-on payment rose from $33.44 to $50.16. We noted that the finalized per training treatment add-on payment amount of $50.16 was in line with the costs reported on the 2010 ESRD facility cost reports, which indicated an average facility training cost of $53.00 per training treatment.

Thus, as stated above, current policies allows ESRD facilities to bill a maximum of 25 training sessions per patient for HHD training. This provides ESRD facilities with payment for 37.5 total hours of training (that is, $1,881.00) for this dialysis modality through the home dialysis training add-on payment adjustment in addition to the training costs that are included in the ESRD PPS bundled payment rate. We believe this provides an adequate opportunity for training of ESRD beneficiaries.

While we have heard from the commenters that we should increase the add-on so that more ESRD patients can receive the benefit of HHD, we have also heard from LDOs that the current training add-on is sufficient. In addition to these differing viewpoints, we've also received information in public comments that indicate a wide variance in training times and the duration of training sessions. In the CY 2014 ESRD PPS final rule, we noted that patient and caregiver commenters indicated a training time for home dialysis training of 2 to 6 weeks in length, with face-to-face nursing time of 2 to 6 hours per training day (78 FR 72184). Commenters also acknowledged that many of the training days took place in the training facility, in a group setting, and not in the patient's home. In addition, some commenters reported that nursing staff were not present for the final week of training, as the patient had achieved total independent self-care (78 FR 72185). We explained that while we believed that an increase in the amount of the home dialysis training add-on payment was appropriate, we were concerned that training services furnished to Medicare beneficiaries appeared inconsistent across training facilities.

Access to care and the well-being of Medicare beneficiaries has always been our primary concern, and we agree that HHD is an important treatment option for patients that can appropriately use this modality. As reflected through the past policies of continuing increased reimbursement through the base rate and the add-on adjustments, we believe we have enhanced, not prevented, access to HHD. In fact, patient use of this treatment modality has increased since the introduction of the ESRD PPS in 2011, according to our monitoring data. We monitor the utilization of home dialysis and provide a quarterly public use file with this information, which is available on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Spotlight.html.* Given the widely varying information we've received about utilization of home dialysis services as well as the differing perspectives on the adequacy of the home dialysis training adjustment, we are committed to conducting further analysis of the this adjustment and will consider making appropriate changes to the adjustment in future rulemaking.

2. Final CY 2016 ESRD PPS Update

a. ESRD Bundled Market Basket

i. Overview and Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD payment amounts are required to be annually increased by an ESRD market basket increase factor that is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

Section 1881(b)(14)(F)(i)(I) of the Act, as added by section 217(b)(2)(A) of PAMA, provides that in order to accomplish the purposes of subparagraph (I) with respect to 2016, 2017, and 2018, after determining the market basket percentage increase factor for each of 2016, 2017, and 2018, the Secretary shall reduce such increase factor by 1.25 percentage points for each of 2016 and 2017 and by 1 percentage point for 2018. Accordingly, for CY 2016, we will reduce the final amount of the market basket percentage increase factor by 1.25 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, and will further reduce it by the productivity adjustment.

ii. Market Basket Update Increase Factor and Labor-Related Share for ESRD Facilities for CY 2016

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRDB input price index (75 FR 49151 through 49162) and subsequently revised and rebased the ESRDB input price index in the CY 2015 ESRD final rule (79 FR 66129 through 66136). Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also

commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket,'' as used in this document, refers to the ESRDB input price index.

We proposed to use the CY 2012-based ESRDB market basket to compute the CY 2016 ESRDB market basket increase factor and labor-related share. We proposed an ESRDB market basket update of 2.0 percent, based on the IHS Global Insight 1st quarter 2015 forecast (with historical data through the 4th quarter of 2014). Also, as required by section 1881(b)(14)(F)(I)(i) of the Act as amended by section 217(b)(2)(A) of PAMA, we proposed to reduce the amount of the market basket increase factor by 1.25 percent, resulting in a proposed CY 2016 ESRDB market basket percentage increase factor of 0.75 percent.

For the CY 2016 ESRD payment update, we proposed to continue using a labor-related share of 50.673 percent for the ESRD PPS payment, which was finalized in the CY 2015 ESRD final rule (79 FR 66136). We implemented the new labor-related share using a 2-year transition of 46.205 percent for CY 2015 and 50.673 percent for CY 2016 (79 FR 66142).

We did not receive any comments on our proposed market basket update. Therefore, based on the most recent forecast available, we are finalizing a CY 2016 ESRDB market basket update of 1.8 percent, based on the IHS Global Insight 3rd quarter 2015 forecast (with historical data through the 2nd quarter 2015). We are also further reducing the 1.8 percent ESRDB market basket update by 1.25 percent as required by section 217(b)(2)(A) of PAMA. Therefore the CY 2016 market basket percentage increase factor is 0.55 percent.

iii. Productivity Adjustment

The productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment'').

The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data. MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI. As described in the CY 2012 ESRD PPS final rule (76 FR 40503 through 40504), to generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. In the CY 2012 ESRD PPS final rule, we identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series.

We proposed that beginning in CY 2016, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs (for details see 80 FR 37825). To summarize the proposed change, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we proposed to use IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with the CY 2016 rulemaking cycle. A complete description of the MFP projection methodology is available on our Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* We also proposed that in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

The proposed CY 2016 MFP adjustment was 0.6 percent based on IGI's 1st quarter 2015 forecast (with historical data through the 4th quarter 2014). We invited comments on the MFP proposal.

Comment: One commenter stated that, using IGI's first quarter 2015 forecast, the MFP adjustment for CY 2016 (the 10 year moving average of MFP for the period ending CY 2016) is projected to be 0.6 percent. The commenter asked what other firms suggest for projected MFP and why are we basing the MFP solely on a single quarter's forecast.

Response: IHS Global Insight (IGI), Inc. is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets and multifactor productivity (MFP). We do not purchase additional forecasts of MFP or other economic series from separate consulting firms.

The MFP adjustment is based on the 40 quarter (or 10-year) moving average of changes in economy-wide private non-farm MFP. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be aligned with the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period). Therefore, the commenter is incorrect that the MFP is based solely on a single quarter's forecast because, in actuality, the MFP adjustment reflects 40 quarters worth of data through the 4th quarter of 2016.

We did not receive any comments related to our proposal to change the capital input series in the MFP formula. Therefore, based on the most recent forecast available, we are finalizing a CY 2016 MFP adjustment of 0.4 percent, based on the IHS Global Insight 3rd quarter 2015 forecast (this reflects historical MFP data through 2014).

iv. Calculation of the ESRDB Market Basket Update, Adjusted for Multifactor Productivity for CY 2016

As required by section 1881(b)(14)(F) of the Act, which requires the ESRD PPS to be updated by the market basket reduced by the MFP adjustment, as well as section 1881(b)(14)(F)(i)(I) of the Act, as amended by section 217(b)(2)(A)(ii) of PAMA, which requires a 1.25 percentage point reduction to the ESRDB market basket increase factor, the proposed CY 2016 ESRD market basket increase was 0.15 percent (2.0 percent market basket update less 1.25 percent PAMA reduction, less 0.6 percentage point MFP update). We also noted that if more recent data is subsequently available we would use such data to determine the final CY 2016 market basket update and MFP adjustment in the ESRD PPS final rule.

Therefore, using the most recent data available, the final CY 2016 ESRDB market basket less MFP update is 0.15 percent. This is based on a 1.8 percent market basket update, less a 1.25 percent adjustment as required by section 1881(b)(14)(F)(i)(I) of the Act, as amended by section 217(b)(2)(A)(ii) of PAMA, and further reduced by a 0.4 percent MFP update. The CY 2016 ESRDB market basket update and MFP adjustment are based on the IHS Global Insight 3rd quarter 2015 forecast with historical data through the 2nd quarter 2015.

b. The Final CY 2016 ESRD PPS Wage Indices

i. Annual Update of the Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized the use of the Office of Management and Budget's (OMB) Core-Based Statistical Areas (CBSAs)-based geographic area designations to define urban and rural areas and their corresponding wage index values.

In the CY 2016 ESRD PPS proposed rule (80 FR 37825), we stated that we would continue to use the same methodology as finalized in the CY 2011 ESRD PPS final rule (75 FR 49117) for determining the wage indices for ESRD facilities. Specifically, we are updating the wage indices for CY 2016 to account for updated wage levels in areas in which ESRD facilities are located. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient prospective payment system. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under section 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The final CY 2016 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the final CY 2016 wage index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.*

In the CY 2011 and CY 2012 ESRD PPS final rules (75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively), we also discussed and finalized the methodologies we use to calculate wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the State and use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area.

For CY 2016, we are applying this criteria to American Samoa and the Northern Mariana Islands, where we apply the wage index for Guam as established in the CY 2014 ESRD PPS final rule (78 FR 72172) (0.9611), and Hinesville-Fort Stewart, Georgia, where we apply the statewide urban average based on the average of all urban areas within the state (78 FR 72173) (0.8666). We note that if hospital data becomes available for these areas, we will use that data for the appropriate CBSAs instead of the proxy.

A wage index floor value has been used in lieu of the calculated wage index values below the floor in making payment for renal dialysis services under the ESRD PPS. In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized that we would continue to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition. In the CY 2012 ESRD PPS final rule (76 FR 70241), we finalized the 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.5500 and 0.5000, respectively. We continued to apply and to reduce the wage index floor by 0.05 in the CY 2013 ESRD PPS final rule (77 FR 67459 through 67461). Although our intention initially was to provide a wage index floor only through the 4-year transition to 100 percent implementation of the ERSD PPS (75 FR 49116 through 49117; 76 FR 70240 through 70241), in the CY 2014 ESRD PPS final rule (78 FR 72173), we continued to apply the wage index floor and continued to reduce the floor by 0.05 per year for CY 2014 and for CY 2015.

For CY 2016, we proposed to continue to apply the CY 2015 wage index floor, that is, 0.4000, to areas with wage index values below the floor but we did not propose to reduce the wage index floor for CY 2016. Our review of the wage indices show that CBSAs in Puerto Rico continue to be the only areas with wage index values that would benefit from a wage index floor because they are so low. Therefore, we believe that we need more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor and leave it at 0.4000. Because the wage index floor is only applicable to a small number of CBSAs, the impact to the base rate through the wage index budget-neutrality factor is insignificant. To the extent other geographical areas fall below the floor in CY 2016 or beyond, we believe they should have the benefit of the 0.4000 wage index floor as well. We will continue to review wage index values and the appropriateness of a wage index floor in the future.

ii. Implementation of New Labor Market Delineations

As noted earlier in this section, in the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized for the ESRD PPS the use of the CBSA-based geographic area designations described in OMB bulletin 03–04, issued June 6, 2003, as the basis for revising the urban and rural areas and their corresponding wage index values. This bulletin, as well as subsequent bulletins, is available online at *http://www.whitehouse.gov/omb/bulletins_index2003±2005.*

OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. In accordance with our established methodology, we have historically adopted via rulemaking CBSA changes that are published in the latest OMB bulletin. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.* According to OMB, ''[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and Census Bureau data.'' When referencing the new OMB geographic boundaries of statistical areas, we use the term ''*delineations*'' rather than the term ''*definitions*'' that we have used in the past, consistent with OMB's use of the terms (75 FR 37249). Because the bulletin was not issued until February 28, 2013, with supporting data not available until later, and because the changes made by the bulletin and their ramifications needed to be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of the FY 2014 IPPS/LTCH PPS proposed rule and, thus, did not implement changes to the hospital wage index for FY 2014 based on these new CBSA delineations.

For the same reasons, the CY 2014 ESRD PPS wage index (based upon the pre-floor, pre-reclassified hospital wage data, which is unadjusted for occupational mix) also did not reflect the new CBSA delineations. In the FY 2015 IPPS/LTCH PPS final rule, we

implemented the new CBSA delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, beginning with the FY 2015 IPPS wage index (79 FR 49951 through 49963). Similarly, in the CY 2015 ESRD PPS final rule (79 FR 66137 through 66142), we implemented the new CBSA delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, beginning with the CY 2015 ESRD PPS wage index.

In order to implement these changes for the ESRD PPS, we identified the new labor market area delineation for each county and facility in the country and determined that there would be new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would be split apart. In the CY 2015 final rule (79 FR 66137 and 66138), we provided tables that showed the CBSA delineations and wage index values for CY 2014 and the CY 2015 CBSA delineations, wage index values, and the percentage change in these values for those counties that changed from rural to urban, from urban to rural, and from one urban area to another and also showed the changes to the statewide rural wage index.

While we believe that the new CBSA delineations result in wage index values that are more representative of the actual costs of labor in a given area, we recognized that use of the new CBSA delineations results in reduced payments to some facilities. For this reason, we implemented the new CBSA delineations using a 2-year transition with a 50/50 blended wage index value for all facilities in CY 2015 and 100 percent of the wage index based on the new CBSA delineations in CY 2016. Therefore, for CY 2016, we are completing the transition and will apply 100 percent of the wage index based on the new CBSA delineations and the most recent hospital wage data.

A facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized a policy to use the labor-related share of 41.737 percent for the ESRD PPS which was based on the ESRDB market basket finalized in that rule. In the CY 2015 ESRD PPS final rule (79 FR 66136), we finalized a new labor-related share of 50.673 percent, which was based on the rebased and revised ESRDB market basket finalized in that rule, and transitioned the new labor-related share over a 2-year period. For CY 2015, the labor-related share is based 50 percent on the old labor-related share and 50 percent on the new labor-related share, and the labor-related share in CY 2016 is based 100 percent on the new labor-related share.

The comments we received on wage index issues and our responses are set forth below.

Comment: A large health plan requested that we develop a wage index specific to ESRD facilities. They pointed out that ESRD staffing is inherently different than hospital staffing and that tying the ESRD wage index to hospital wage and staffing patterns does not reflect the true costs of operating an ESRD facility.

Response: We are unable to implement a wage index based on ESRD wage data for CY 2016 as we did not propose to make this change and we do not have sufficient data on ESRD facility wages at this time. In future refinements to the ESRD PPS we will certainly consider the feasibility of this recommendation. However, we note that efforts to develop provider-specific wage indices for other Medicare providers have been unsuccessful from both CMS' and the providers' viewpoints. As a result, we do not intend to consider an ESRD-specific wage index until we can demonstrate that such an index would be more reflective of the wages and salaries paid, that it would significantly improve our ability to determine payment for ESRD facilities, and that we can justify the resources required to collect the data, as well as the increased burden on providers.

Comment: An organization representing small and medium dialysis facilities urged CMS to examine the impact of the wage index on the case-mix adjusters and their value to dialysis facilities. For facilities located in areas where the wage index is below one, the practical effect of the wage index is a lower base rate. In addition, because the case-mix adjusters are calculated as multipliers to the base rate, facilities located in areas where the wage index is below one are receiving less value from the adjusters. Thus, the low wage area facilities are hit twice for the lower wage index. If CMS increases the weight of the case-mix adjusters in the payment formula, the disparities between high wage area and low wage area facilities is further exacerbated.

Response: The case-mix adjusters are estimated controlling for the urban versus rural location of the facilities where labor costs play a significant role in the cost. The case- mix adjusters in the CR part of the model reflect the costs of providing basic dialysis services to patients. These costs, which are largely labor costs, are expected to be lower for facilities in areas with low wage indices. Therefore, it is appropriate that the incremental cost of caring for a patient in the young or very old age category should be proportionately smaller in areas with lower wages. The case-mix adjusters, other than age, apply mainly in the SB equation part of the model. The SB part of the model is not adjusted for wages.

As to the concern that rural facilities are not receiving the full case-mix adjustments, we understand the commenter's concern and intend to continue to examine the impact of the wage index on the case-mix adjusters and the payments made to ESRD facilities, particularly facilities located in areas where the wage index is below one.

Comment: A national dialysis organization expressed support for the wage index proposals and the continued application of the wage index floor where applicable. An organization representing small and medium dialysis facilities asked CMS to implement a freeze in the wage floor to prevent further hardship for rural facilities.

A health plan commented that the proposed 4 percent decrease to the base rate due to refinement will be detrimental to ESRD facilities located in Puerto Rico and urged CMS to re-establish a fair and meaningful wage index floor to substitute for the low wage index values that result from hospital wage data reported in Puerto Rico.

The commenter provided several alternative wage indexes for Puerto Rico for the CY 2016 ESRD PPS final rule: (1) Apply our policies for areas that do not have reliable hospital data, and apply the wage index for Guam as we did in implementing the ESRD PPS in the Northern Marianas and American Samoa, (2) use the U.S. Virgin Islands as a proxy for Puerto Rico given the geographic proximity and its ''non-mainland'' or ''island'' nature, or (3) re-establish the wage index floor in effect in 2010 when Puerto Rico became the only wage areas subject to the floor, that is, 0.65. Finally, the commenter requests that we delay the increase in the labor-related share to which to the wage index is applied for facilities in Puerto Rico because increases in the labor-related share lowers payments for low wage index areas.

Response: For CY 2016, we proposed to continue to apply the CY 2015 wage index floor, that is, 0.4000, to areas with wage index values below the floor, rather than reduce the floor by 0.05 as we have done over the last 10 years. We stated that we need more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the

wage index floor. The commenter has provided useful suggestions that we plan to consider in proposing updates to the wage index policies under the ESRD PPS for CY 2017, so that we may review all options in the future rulemaking, which will allow for public comments.

With regard to delaying implementation of the labor-related share for facilities in Puerto Rico, we believe it is important that we apply the labor-related share derived from the latest update to the ESRDB market basket. We do not believe it would be appropriate to delay implementation longer or to apply the new labor-related share in a non-uniform manner. In addition, a change to the labor-related share does not address the primary issue the commenter identified, which is the comparatively lower wages reported by hospitals in Puerto Rico. For these reasons, we are not making any changes to the labor-related share finalized in the CY 2015 ESRD PPS final rule.

Comment: An MDO requested that we provide them the wage index in an Excel format so that they have access to the county names.

Response: We provide a file that includes the county names with each rule that is issued. The link to the ESRD PPS rules Web page is *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.* The file with county names was available when the CY 2016 ESRD PPS proposed rule was published.

After considering the public comments submitted, we are finalizing the CY 2016 wage index policies as proposed and implementing the CBSA designations based on the latest hospital wage data. In addition, we are maintaining a wage index floor of 0.4000 and continuing our current policies for wage areas with no hospital data.

c. CY 2016 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, comorbidities such as cancer, and possibly race and gender. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy in our regulations at 42 CFR 413.237, which provide that ESRD outlier services are the following items and services that are included in the ESRD PPS bundle: (i) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) medical/surgical supplies, including syringes, used to administer ESRD-related drugs, that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (iv) renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, excluding oral-only drugs used in the treatment of ESRD.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item on the monthly claim. Renal dialysis service drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were originally specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which was issued to correct the subject on the Transmittal page and made no other changes.

Furthermore, we use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. We use this separate guidance to identify renal dialysis service drugs which were or would have been covered under Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we also identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Our regulations at 42 CFR 413.237 specify the methodology used to calculate outlier payments. An ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed-dollar loss amount. In accordance with § 413.237(c) of the regulations, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule, using 2007 data, we established the outlier percentage at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the fixed-dollar loss amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and fixed-dollar loss amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments.

For the CY 2016 outlier policy, we proposed to use the existing methodology for determining outlier payments by applying outlier services payment multipliers that resulted from the updated regression analyses. The updated outlier services payment multipliers are represented by the updated separately billable payment multipliers presented in Table 7 for patients age 18 years and older. We used these updated outlier services payment multipliers to calculate the predicted outlier service MAP amounts and projected outlier payments for CY 2016.

In the CY 2016 ESRD PPS proposed rule (80 FR 37827), we proposed that the outlier services MAP amounts and fixed-dollar loss amounts would be derived from claims data from CY 2014. Because we believe that any adjustments made to the MAP amounts

under the ESRD PPS should be based upon the most recent data year available in order to best predict any future outlier payments, we proposed that the outlier thresholds for CY 2016 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2014. We stated that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and fixed-dollar loss amounts every year under the ESRD PPS. However, we believe for the first time since the implementation of the ESRD PPS that data for CY 2014 reflects relatively stable ESA use. We have included Table 6 below to demonstrate the leveling off of the decline in ESA utilization.

TABLE 6—TOTAL MEDICARE ESA UTILIZATION IN THE ESRD POPULATION

	2009	2010	2011	2012	2013	2014 [1]
Total ESA Utilization:						
Epogen (x100,000)	2,083,893	2,075,217	1,655,778	1,319,383	1,262,186	1,143,405
Darbepoetin (x100,000)	533	496	379	280	242	291
ESA Utilization per Session:						
Epogen	5,404	5,171	3,995	3,078	2,895	2,858
Darbepoetin	1.38	1.24	0.91	0.65	0.55	0.73

[1] 2014 based on December 2014 claims.

i. CY 2016 Update to the Outlier Services MAP Amounts and Fixed-Dollar Loss Amounts

For CY 2016, we did not propose any changes to the methodology used to compute the MAP or fixed-dollar loss amounts. Rather, the proposed rule updated the outlier services MAP amounts and fixed-dollar loss amounts to reflect the utilization of outlier services reported on 2014 claims using the December 2014 claims file. For this final rule, the outlier services MAP amounts and fixed dollar loss amounts were updated using the 2014 claims from the June 2015 claims file. The impact of this update is shown in Table 7, which compares the outlier services MAP amounts and fixed-dollar loss amounts used for the outlier policy in CY 2015 with the updated estimates for this rule. The estimates for the final CY 2016 outlier policy, which are included in Column II of Table 7, were inflation adjusted to reflect projected 2016 prices for outlier services.

TABLE 7—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I Final outlier policy for CY 2015 (based on 2013 data price inflated to 2015) *		Column II Final outlier policy for CY 2016 (based on 2014 data price inflated to 2016) *	
	Age <18	Age >= 18	Age <18	Age >= 18
Average outlier services MAP amount per treatment	$39.89	$52.98	$40.20	$53.29
Adjustments:				
Standardization for outlier services	1.1145	0.9878	0.9951	0.9729
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$43.57	$51.29	$39.20	$50.81
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$54.35	$86.19	$62.19	$86.97
Patient months qualifying for outlier payment	6.3%	6.3%	5.8%	6.5%

As demonstrated in Table 7, the estimated fixed-dollar loss amount per treatment that determines the CY 2016 outlier threshold amount for adults (Column II; $86.97) is slightly higher than that used for the CY 2015 outlier policy (Column I; $86.19). The lower threshold is accompanied by a decline in the adjusted average MAP for outlier services from $51.29 to $50.81. For pediatric patients, the fixed dollar loss increased from $54.35 to $62.19. Likewise, the adjusted average MAP for outlier services fell from $43.57 to $39.20.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2016 will be 6.5 percent for adult patients and 5.8 percent for pediatric patients, based on the 2014 claims data. The pediatric outlier MAP and fixed-dollar loss amounts continue to be lower for pediatric patients than adults due to the lower use of outlier services (ESAs and other injectable drugs) in the pediatric population.

ii. Outlier Policy Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081), in accordance with 42 CFR 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments. Based on the 2014 claims from the June 2015 claims file, outlier payments represent approximately 0.8 percent of total payments, slightly below the 1 percent target due to small declines in the use of outlier services. Recalibration of the thresholds using 2014 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2016. We believe the update to the outlier MAP and fixed-dollar loss amounts for CY 2016 will increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier target. We note that the recalibration of the fixed-dollar loss amounts that are being finalized in this rule will result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but will increase payments to ESRD facilities for beneficiaries with renal dialysis items

and services that are eligible for outlier payments. Therefore, beneficiary co-insurance obligations would also increase for renal dialysis services eligible for outlier payments.

In the CY 2016 ESRD PPS proposed rule (80 FR 37828), we noted that many industry stakeholder associations and renal facilities have expressed disappointment that the outlier target percentage has not been achieved under the ESRD PPS and have asked that CMS eliminate the outlier policy. We further stated that with regard to the suggestion that we eliminate the outlier adjustment altogether, under section 1881(b)(14)(D)(ii) of the Act, the ESRD PPS must include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of ESAs necessary for anemia management. We believe that the ESRD PPS is required to include an outlier adjustment in order to comply with section 1881(b)(14)(D)(ii) of the Act.

In addition, we believe that the ESRD PPS base rate captures the cost for the average renal patient, and to the extent data analysis continues to show that certain patients, including certain racial and ethnic groups, receive more ESAs than the average ESRD patient, we believe an outlier policy, even a small one, is an important payment adjustment to provide under the ESRD PPS. We did not propose to modify the 1 percent outlier percentage for CY 2016 because we believe that the regression analysis continues to demonstrate high cost patients and that the elimination of the comorbidity categories of bacterial pneumonia and monoclonal gammopathy and other regression updates would assist facilities in receiving outlier payments in CY 2016 that are 1.0 percent of total ESRD PPS payments.

In the proposed rule (80 FR 37829), we further stated that we understand the industry's frustration that payments under the outlier policy have not reached 1.0 percent of total ESRD PPS payments since the implementation of the payment system. As we explained in the CY 2014 ESRD PPS final rule (78 FR 72165), each year we simulate payments under the ESRD PPS in order to set the outlier fixed-dollar loss and MAP amounts for adult and pediatric patients to try to achieve the 1.0 percent outlier policy. We would not increase the base rate to account for years where outlier payments were less than 1.0 percent of total ESRD PPS payments, nor would we reduce the base rate if the outlier payments exceed 1 percent of total ESRD PPS payments.

We believe the 1.0 percent outlier percentage has not been reached under the payment system due to the significant drop, over 25 percent, in the utilization of high cost drugs such as Epogen since the implementation of the payment system. In other words, the shortfall in outlier payments is likely to arise precisely because facilities are incurring lower costs than they did in the historical data used to set the base rate. However, we have learned in our discussions with ESRD facilities that some facilities might not report outlier services on the ESRD facility monthly claim form as they do not believe that they will reach the outlier threshold. We issued sub-regulatory guidance for CY 2015 that instructs ESRD facilities to include all composite rate drugs and biologicals furnished to the beneficiary on the monthly claim form (Change Request 8978, issued December 2, 2014). In CY 2015 ESRD PPS final rule (79 FR 66149 through 66150), we discussed the drug categories that we consider to be used for the treatment of ESRD with the expectation that all of those drugs and biologicals would be reported on the claim. In addition to this guidance, we also have included a clarification for how facilities are to report laboratory services and drugs and biologicals on the monthly claim form. We believe these steps will lead to an increase in outlier payments in CY 2016.

The comments we received on the outlier policy update for CY 2016 and our responses are set forth below.

Comment: An organization representing small and medium dialysis facilities stated that if CMS is unable to distribute the entire one percent of the holdback, the amount of the outlier holdback should be lowered. An organization of nonprofit SDOs agreed, indicating that the outlier factor should be reduced to 0.5 percent, which is closer to the actual rate of outlier payments that have been made since 2011. A nonprofit dialysis organization would prefer that the outlier provision be removed from the bundled payment system, but at a minimum, the outlier target percentage should be reduced from 1.0 percent to 0.5 percent. A large national dialysis organization expressed support for the outlier policy as an alternative to the comorbidity adjustments. A professional association also expressed support for the outlier policy.

An MDO pointed out that the ESRD PPS paid 0.9 percent of the 1.0 percent outlier target and asked what the dollar amount difference was and how many Medicare claims in 2014 received an outlier payment. They commented that this amount could be added back to the base rate for CY 2016 because they believe the fact that the full outlier holdback was not paid out means ESRD facilities essentially lost out on this money. A professional association supports the concept of an outlier policy to sufficiently reimburse dialysis facilities for high-cost patients. However, they are concerned that the current policy is flawed based on the low percentage of facilities that qualify for outlier payments. They suggest one of two options to ensure disbursement of this withholding: (1) An annual adjustment of the threshold for outlier payments to fully expend the withholding; or (2) an annual adjustment of the withholding based on the running average of the expenditure from the prior 3 years, with the total withholding not to exceed 1.0 percent. Another organization urged CMS to examine whether outlier payments are being received by the facilities that truly need them.

Response: We appreciate the commenters' support for the outlier policy. As we explained in the proposed rule and above, our analysis of ESRD PPS claims show that outlier payments reached 0.8 percent of the 1.0 percent outlier target in 2014. Specifically, outlier payments were made for 185,293 patient months, totaling $71,325,656 ($89,157,069 when including patient or secondary insurer obligations). For these patient months, outlier payments represented 16.2 percent of total Medicare payments. 5,992 facilities received at least one outlier payment. Twenty percent of outlier payments in dollars were received by independent facilities and another 13 percent were received by facilities that were part of a multi-facility organization other than the three largest chains. Outlier payments are particularly important for small dialysis organizations and independent dialysis facilities because they often lack the volume of patients necessary to offset the high cost of certain patients. With regard to the comment that the outlier policy is flawed based on the low percentage of facilities that qualify for outlier payments, we note that 94 percent of facilities received outlier payments. Further, the 1.0 percent outlier target is small compared to outlier policies in other Medicare payment systems and was not designed to cover a large number of claims. As indicated in Table 7, we estimate that the percentage of patient months qualifying for outlier payments in CY 2016 will be 6.5 percent for adult patients and 5.8 percent for pediatric patients, based on the 2014 claims data.

We acknowledge that the 1.0 percent target has not been achieved since 2011 primarily because our annual update of the fixed-dollar loss amounts and MAP amounts could not keep up with the continued decline in the use of outlier services (primarily ESAs). That is, facilities incurred lower costs than anticipated, and those savings accrued to facilities more than offsetting the extent to which the consequent outlier payments fell short of the 1.0 percent target. However, as we stated in the proposed rule and above, we now believe that decline is leveling off, which will make our projections of outlier payments more accurate. In addition, because we are deleting two comorbidity category adjustments (bacterial pneumonia and monoclonal gammopathy) for CY 2016, we believe it is important to maintain the current 1.0 percent outlier policy. By doing so, the ESRD PPS protects patient access by providing additional payment for patients whose care requires more outlier services than the average patient.

With regard to the suggestion that we annually adjust the withholding based on the running average of the expenditure from the prior three years, with the total withholding not to exceed 1.0 percent, as we explain above, each year we simulate payments under the ESRD PPS in order to set the outlier fixed-dollar loss and MAP amounts for adult and pediatric patients to try to achieve the 1.0 percent outlier policy. We would not increase the base rate to account for years where outlier payments were less than 1.0 percent of total ESRD PPS payments and, more importantly we would not reduce the base rate if the outlier payments exceed 1.0 percent of total ESRD PPS payments. Rather than increasing and decreasing the base rate, we re-estimate the fixed-dollar loss threshold and MAP amounts so that outlier payments in the following year are 1.0 percent of total ESRD PPS payments. This is the approach used in other Medicare payment systems that include an outlier policy, such as the Inpatient Psychiatric Facility PPS. As we have done since 2011, we will continue to monitor outlier payments and assess annually the extent to which adjustments need to be made in the fixed-dollar loss and MAP amounts in order to achieve outlier payments that are 1.0 percent of total ESRD PPS payments.

d. Annual Updates and Policy Changes to the CY 2016 ESRD PPS

i. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we discussed the implementation of the ESRD PPS per treatment base rate that is codified in the Medicare regulations at § 413.220 and § 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate, outlier payments, and geographic wage index budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims, that is, the lowest per patient utilization year from the 2006 through 2008 time period, as required by section 1881(b)(14)(A)(ii) of the Act, updated to CY 2011, and represented the average per treatment MAP for renal dialysis services. The payment system is updated annually by the ESRDB market basket less the productivity adjustment which is discussed in section II.B.2.of this final rule.

ii. Annual Payment Rate Update for CY 2016

We proposed an ESRD PPS base rate for CY 2016 of $230.20. This update reflected several factors, described in more detail below.

Market Basket Increase: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2016 projection for the ESRDB market basket was 2.0 percent. In CY 2016, this amount must be reduced by 1.25 percentage points as required by section 1881(b)(14)(F)(i)(I), as amended by section 217(b)(2)(A) of PAMA, which is calculated as $2.0 - 1.25 = 0.75$. This amount is then further reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as required by section 1881(b)(14)(F)(i)(II) of the Act. The proposed multi-factor productivity adjustment for the CY 2016 proposed rule was 0.6, yielding a proposed update to the base rate of 0.15 percent for CY 2016 ($0.75 - 0.6 = 0.15$ percent).

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2016, we did not propose any changes to the methodology used to calculate this factor, which is described in detail in CY 2014 ESRD PPS final rule (78 FR 72174). The CY 2016 proposed wage index budget-neutrality adjustment factor was 1.000332.

Refinement Budget-Neutrality Adjustment Factor: In order to implement the refinement in a budget-neutral manner, we proposed to adjust the ESRD PPS base rate by a budget-neutrality adjustment factor. In CY 2011, we standardized the base rate to account for the overall effects of the ESRD PPS adjustment factors by making a 5.93 percent reduction to the base rate. To account for the overall effects of the refinement (that is, to not increase Medicare spending), we proposed a negative 4 percent adjustment (that is, a factor of 0.959703) to the ESRD PPS base rate to account for the additional dollars paid to facilities through the payment adjustments. While the per-treatment base rate would be reduced, we believe that this refinement improves payment accuracy and we would expect payments to be better targeted to those characteristics that increase costs for facilities. Notably, a significant portion of the downward effect on the base rate is due to the higher payments resulting from changes in the age adjustments. However other changes, such as using the prevalence of comorbidities on the ESRD facility claim, has an upward effect on the refinement budget-neutrality adjustment factor.

In summary, we proposed a CY 2016 ESRD PPS base rate of $230.20. This reflects a market basket increase of 0.15 percent, the CY 2016 wage index budget-neutrality adjustment factor of 1.000332, and the refinement budget-neutrality adjustment of 0.959703.

The comments and our responses are set forth below.

Comment: Several dialysis organizations recommended that the standardization factor applied to the base rate be updated annually to reflect the actual prevalence of the payment adjustors. The organizations pointed out that between 2011 and 2014, the ESRD PPS underpaid providers by more than $844 million relative to CMS' projections in the ESRD PPS final rules for those years. They stated that the underpayments are the direct result of CMS' policies and methodological flaws in calculating the payment adjusters and the outlier pool.

An organization representing small and medium dialysis facilities sponsored an analysis that found that from 2012 to 2013, providers were underpaid by an estimated $33 million, or $.019 per treatment because the actual prevalence of the case-mix adjusters did not align with CMS' assumptions. The organization pointed out that the estimates of the prevalence of comorbid conditions in the 2016 refinement is well below the estimate

made in 2011. A nonprofit dialysis organization pointed out that because of the burden associated with comorbidity adjustments, providers are not able to report comorbidities to the extent predicted by CMS. As a result, CMS is paying less per treatment than anticipated. They urged CMS to update the standardization factor. The organizations stated that since the original base rate was set assuming a much higher prevalence of these conditions, it would appear that the ESRD PPS did not achieve budget neutrality with the prior payment system. The organization believes CMS should re-estimate the original standardization factor to account for the lower prevalence of the comorbidity adjustments and use this base rate as the starting point for any changes in 2016. This will ensure that overall budget neutrality is ensured within the ESRD PPS and prevent CMS from locking in the underpayments from the last several years into perpetuity. Going forward, they urged CMS to monitor the impact of the case-mix adjusters to ensure that actual prevalence of the adjusters is keeping pace with the original estimates and that the expected levels of payment are being realized.

Response: The refinement budget-neutrality adjustment supplements the standardization factor. This is because the value of the adjusters following the 2016 refinement has increased. As such, it would be inappropriate to recalibrate the standardization adjustment because the value of this adjustment together with the 4 percent refinement budget-neutrality adjustment is equal to the updated adjuster values calculated using updated data. The 4 percent increase, primarily the result of the updated age adjusters, is expected to be paid out to ESRD facilities because they are based on information required to be included on every claim (the patients' birth date) and therefore, there is no documentation burden.

With respect to the suggestion that we update the budget-neutrality adjustment factor annually to reflect the actual prevalence of the payment adjustors, we do not believe this is the best approach. We would not want to increase or decrease the base rate based on the prevalence of the payment adjusters in one year. Instead, as we have done since 2011, we intend to monitor the prevalence of the case-mix adjusters to ensure that actual prevalence of the adjusters is keeping pace with the original estimates.

Comment: Several dialysis organizations commented that they are deeply concerned by the reduction of the base rate for CY 2016. They indicated that the proposed rule does not contain sufficient information to determine the relationship between the standardization factor applied to the base rate in 2011 and the refinement budget-neutrality adjustment factor. For example, they note it is not possible from the preamble to determine whether the contractor used the actual frequency of adjusters applied to the 2013 claims to derive a standardization factor that is the sum of the previous standardization factor and the refinement budget-neutrality adjustment factor. The indicated that it appears that the significant reduction in the base rate is due to the inappropriate increase in the age adjuster. They request that we recompute the standardization factor and refinement budget-neutrality adjustment factor based on their recommended changes in the model and provide sufficient information in the final rule to allow stakeholders to understand the interaction of the two budget-neutrality factors.

Response: As discussed above, the refinement budget-neutrality adjustment accounts for the increase in the value of the adjusters above the value already accounted for by the standardization adjustment. Thus, the total value of the revised adjusters is represented by the standardization factor plus the refinement budget-neutrality adjustment. In other words, the standardization adjustment reflected the adjuster values as calculated in 2011 and when we used updated data to calculate the values for 2016, we needed to determine the extent to which the new values diverged from the values that were accounted for in the standardization adjustment when the ESRD PPS was implemented. Because the values increased in the refinement, we needed a further reduction to the base rate in addition to the standardization adjustment, which was applied in the form of the refinement budget-neutrality adjustment.

In terms of the commenters' point about the age adjustment, as discussed above, we believe the methodology for our regression was sound and we do not believe the increased value of the age adjusters is inappropriate. Moreover, we believe the increased value of the age adjusters is beneficial to ESRD facilities because they will always be paid out. This is because patient age is already captured on ESRD facility claims. As long as the patient is in one of the age categories for which we have a payment adjustment, the ESRD facility will always receive the adjustment without any added burden to document the patient's age.

We used the data from CY 2012 and CY 2013 to set the adjustment factors and then applied those factors to the CY 2014 claims to determine the budget-neutrality factor associated with this refinement. The final refinement budget-neutrality adjustment factor is not the sum of the standardization factor computed for the CY 2011 rule and the budget-neutrality factor associated with the refinement. Rather, we used the CY2014 claims to estimate payments under the PPS for CY2016 both when applying the original payment adjustment factors that have been used since CY2011 and when applying the modified payment adjustment factors that were developed for this refinement. The refinement budget-neutrality factor was then calculated as the ratio of these two total estimated payment amounts. Note that neither of these total estimated payment amounts included the estimated outlier payments because they are added separately in determining the total payment for each claim.

The calculation described above resulted in a factor of 0.959703 that was applied as a reduction to the base rate amount in the proposed rule due to the overall larger payment adjustments to be made under the PPS due to the proposed refinement. The commenter is correct that this reduction in the base rate resulted primarily from the change in the age multipliers estimated using 2012 through 2013 data compared to those estimated for the 2011 model using 2006 through 2008 data. Concerns about the age multipliers are addressed in responses to other comments in section II.B.1.c.i of this final rule. Notably, the prevalence of comorbidities for this refinement was assessed based only on comorbidities reported on CY2014 dialysis facility claims for payment as case-mix adjusters. This decreased the estimated prevalence of those case-mix adjusters relative to the process used for the CY2011 final rule, which based prevalence estimates on multiple claims types from other providers.

Comorbidities represent less of the total value of the adjusters than they did before the refinement and age represents much more of the value of the adjusters than they did before the refinement. We believe this will be a positive change for facilities because the age adjustment should pay out in full without any added documentation burden. When repeating the calculation described above with updated CY2014 claims data, we are finalizing an updated refinement budget-neutrality factor of 0.960319.

With regard to the reduction to the base rate for CY 2016, the refinement

modeling which relies on ESRD facility claims and cost reports shifts the emphasis away from comorbidities (which proved difficult for facilities to obtain and now have less of an impact on the refinement budget-neutrality adjustment factor) to the age adjustments, which should be paid out. While the base rate has been further reduced by 4 percent to account for the increased value of the payment adjusters following the refinement, maintaining five age categories makes it more likely that ESRD facilities will receive sufficient payment to offset the reduction to the base rate.

Comment: An MDO stated that they do not support the refinement budget-neutrality adjustment factor because it is forcing the base rate to be less than it could be. They indicated that the base rate should not be decreasing on an annual basis. An organization representing small and medium dialysis facilities commented that it is necessary and appropriate for the ESRD PPS to contain case-mix adjustments, however, the proposal to reduce the base rate to allow for the increased value of some case-mix adjusters will create greater payment risk for dialysis facilities and add further complexity to an already complicated payment system. The organization suggests that rather than increasing the value of the case-mix adjusters, CMS should increase the value of the base rate. Ensuring an adequate base rate will minimize loss in payment to providers due to flaws in the case-mix adjustment formula. An SDO recommended that CMS avoid placing so much emphasis on payment adjusters that the ESRD PPS base rate is reduced to $230.20.

Response: The refinement budget-neutrality adjustment factor is applied to pay for the increased value of the payment adjustments provided under the ESRD PPS following our updated regression analysis. In complying with the ATRA requirement to revise the case-mix adjustments in CY 2016, we had to apply a refinement budget-neutrality factor so that the refinement did not increase Medicare spending. We believe, however, that the adjustment values are more accurate and will be paid out more easily and therefore, although the base rate is reduced, ESRD facilities should receive additional payments through the payment adjustments. With regard to the comment that the base rate should not be decreasing on an annual basis, the reductions to the base rate were required by section 1881(b)(14)(F)(i)(I) of the Act, as amended by section 217(b)(2)(A) of PAMA) and are applied in lieu of the drug utilization adjustment implemented in the CY 2014 ESRD PPS final rule (78 FR 72161).

In summary, for CY 2016 we are finalizing a base rate of $230.39. For this rule, the latest projection for the ESRDB market is 1.8 percent. As we stated above, in accordance with section 1881(b)(14)(F)(i)(I) of the Act, for CY 2016 this amount is reduced by 1.25 percent, which is calculated as $1.8 - 1.25 = 0.55$. This amount is further reduced by the final CY 2016 multifactor productivity adjustment of 0.4, thus yielding a final update to the base rate of 0.15 percent for CY 2016 ($0.55 - 0.4 = 0.15$). Therefore, the CY 2015 ESRD PPS base rate of $239.43 is updated to $239.79 ($239.43 × 1.0015 = $239.79). Next, we applied the final wage index budget-neutrality adjustment factor of 1.000495 to yield a wage-adjusted base rate of $239.91 ($239.79 × 1.000495 = $239.91). Our last step in setting the base rate for CY 2016 is to apply the refinement budget-neutrality adjustment factor of 0.960319. The final CY 2016 ESRD PPS base rate is $230.39 ($239.91 × 0.960319 = $230.39).

3. Section 217(c) of PAMA and the ESRD PPS Drug Designation Process

As part of the CY 2016 ESRD PPS rulemaking, section 217(c) of PAMA requires the Secretary to implement a drug designation process for—

(1) Determining when a product is no longer an oral-only drug; and

(2) Including new injectable and intravenous products into the bundled payment under such system.

In accordance with section 217(c) of PAMA, we proposed a process that would allow us to recognize when an oral-only renal dialysis service drug or biological is no longer oral only and to include new injectable and intravenous products into the ESRD PPS bundled payment, and, when appropriate, to modify the ESRD PPS payment amount to reflect the costs of furnishing a new injectable or intravenous renal dialysis service drug or biological that is not bundled in the ESRD PPS payment amount. We believe that this process, which we refer to as the drug designation process under the ESRD PPS, will provide a systematic method for including new injectable and intravenous drugs and biologicals that are designated as renal dialysis services in the ESRD PPS bundled payment.

a. Background

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement the ESRD PPS, under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. The renal dialysis services that are included in the ESRD PPS bundle are described in section 1881(b)(14)(B) of the Act and include: (i) items and services included in the composite rate for renal dialysis services as of December 31, 2010; (ii) erythropoiesis stimulating agents (ESAs) and any oral form of such agents that are furnished to individuals for the treatment of ESRD; (iii) other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately under Title XVIII of the Act, and any oral equivalent form of such drug or biological; and (iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of ESRD.

We implemented the ESRD PPS in the CY 2011 ESRD PPS final rule (75 FR 49030 through 49214) and codified the definition of renal dialysis services at 42 CFR 413.171. In addition to former composite rate items and services and ESAs, we defined renal dialysis services at 42 CFR 413.171 as including other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form). In the CY 2011 ESRD PPS final rule (75 FR 49037 through 49053), we discussed the other drugs and biologicals referenced in paragraph (3) of the definition ''Renal dialysis services'' at 42 CFR 413.171 and finalized how they were included in the ESRD PPS. We explained that we interpreted clause (iii) as encompassing not only injectable drugs and biologicals (other than ESAs) used for the treatment of ESRD, but also all non-injectable drugs furnished under Title XVIII of the Act (75 FR 49039). Under this interpretation, the *any oral equivalent form of such drug or biological* language pertains to the oral versions of injectable drugs other than ESAs. In addition, as we discussed in section II.B.4 of the final rule (75 FR 49040), we concluded that, to the extent oral-only drugs and biologicals that are used for the treatment of ESRD do not fall within clause (iii) of the statutory definition of renal dialysis services, such drugs would fall under clause (iv).

In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053), we explained that to identify drugs and biologicals that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services that would be included in the ESRD PPS base rate, we performed an extensive

analysis of Medicare payments for Part B drugs and biologicals billed on ESRD claims and evaluated each drug and biologicals to identify its category by indication or mode of action. We also explained that categorizing drugs and biological on the basis of drug action would allow us to determine which categories (and therefore, the drugs and biologicals within the categories) would be considered used for the treatment of ESRD (75 FR 49047).

Using this approach, in our CY 2011 ESRD PPS final rule we established categories of drugs and biologicals that are *not* considered used for the treatment of ESRD (75 FR 49049–49051), categories of drugs and biologicals that are *always* considered used for the treatment of ESRD, and categories of drugs and biologicals that *may be* used for the treatment of ESRD but are also commonly used to treat other conditions. Those drugs and biologicals that were identified as *not* used for the treatment of ESRD were not considered renal dialysis services and were not included in computing the base rate. The categories of drugs and biologicals that were always considered used for the treatment of ESRD were identified as access management, anemia management, anti-infectives (specifically vancomycin and daptomycin used to treat access site infections), bone and mineral metabolism, and cellular management (75 FR 49050). As we noted in the CY 2016 ESRD PPS proposed rule (80 FR 37830), we removed anti-infectives from the list of categories of drugs and biologicals that are included in the ESRD PPS base rate and not separately payable in the CY 2015 ESRD PPS final rule (79 FR 66149 through 66150). The categories of drugs that were always considered used for the treatment of ESRD have otherwise remained unchanged since we finalized them in the CY 2011 ESRD PPS final rule. The current categories of drugs that are included in the ESRD PPS base rate and that may be used for the treatment of ESRD but are also commonly used to treat other conditions are antiemetics, anti-infectives, antipruritics, anxiolytics, drugs used for excess fluid management, drugs used for fluid and electrolyte management including volume expanders, and pain management (analgesics) (79 FR 66150).

In the CY 2011 ESRD PPS final rule (75 FR 49050), we explained that for those categories of drugs and biologicals that are always considered used for the treatment of ESRD we used the payments for the drugs included in the category in computing the ESRD PPS base rate, that is, the injectable forms (previously covered under Part B) and oral or other forms of administration (covered under Part D). For purposes of the inclusion of payments related to the oral or other forms of administration for those drugs that are always considered used for the treatment of ESRD, we stated that based on our determination at the time of the final rule, there were oral or other forms of injectable drugs only for the bone and mineral metabolism and cellular management categories. Therefore, we included the payments under Part D for oral vitamin D (calcitrol, doxercalcitrol and paracalcitrol) and oral levocarnitine in our computation of the base rate (75 FR 49042).

In response to a commenter's request to provide a specific list of ESRD-only drugs in the CY 2011 ESRD PPS final rule, we explained that we chose to identify ESRD drugs and biologicals by category rather than in a specific list because using categories of drugs and biologicals allows us to respond to changes in drug therapies over time based upon many factors including new developments, evidence-based medicine, and patient outcomes (75 FR 49050). By categorizing drugs and biologicals based on drug action, we can account for other drugs and biologicals that may be used for those same actions in the future under the ESRD PPS. We further explained that, while we have included drugs and biologicals used in 2007 in the final ESRD base rate, we recognize that these may change. Because there are many drugs and biologicals that have many uses and because new drugs and biologicals are being developed, we stated that we did not believe that a drug-specific list would be beneficial (75 FR 49050).

Rather than specifying the specific drugs and biologicals used for the treatment of ESRD, we identified drugs and biologicals based on the mechanism of action. We stated that we did not finalize a specific list of the drugs and biologicals because we did not want to inadvertently exclude drugs that may be substitutes for drugs identified and we wanted the ability to reflect new drugs and biologicals as they become available. We did, however, provide a list of the specific Part B drugs and biologicals that were included in the proposed and final ESRD PPS base rate in Table C in the Appendix to the CY 2011 ESRD PPS final rule (75 FR 49205 through 49209) and a list of the former Part D drugs that were bundled in the ESRD PPS in Table D in the Appendix to that rule (75 FR 49210). We emphasized that drugs or biologicals furnished for the purpose of access management, anemia management, vascular access or peritonitis, cellular management and bone and mineral metabolism will be considered a renal dialysis service under the ESRD PPS and will not be eligible for separate payment. We also noted that any ESRD drugs or biologicals developed in the future that are administered by a route of administration other than injection or oral would be considered renal dialysis services and would be in the ESRD PPS bundled base rate. We also stated that any drug or biological used as a substitute for a drug or biological that was included in the ESRD PPS bundled base rate would also be a renal dialysis service and would not be eligible for separate payment (75 FR 49050).

In the CY 2011 ESRD PPS final rule (75 FR 49050 through 49051), we explained that for categories of drugs and biologicals that may be used for the treatment of ESRD but are also commonly used to treat other conditions, we used the payments made under Part B in 2007 for these drugs in computing the ESRD PPS base rate, which only included payments made for the injectable forms of the drugs. We excluded the Part D payments for the oral (or other form of administration) substitutes for the drugs and biologicals described above because they were not furnished or billed by ESRD facilities or furnished in conjunction with dialysis treatments (75 FR 49051). For those reasons, we presumed that these drugs and biologicals that were paid under Part D were prescribed for reasons other than for the treatment of ESRD. However, we noted that if these drugs and biologicals currently paid under Part D are furnished by an ESRD facility for the treatment of ESRD, they would be considered renal dialysis services and we would not provide separate payment.

In the CY 2011 ESRD PPS final rule (75 FR 49075), we included in Table 19 the Medicare allowable payments for all of the components of the ESRD PPS base rate for CY 2007 inflated to CY 2009, including payments for drugs and biologicals and the amount each contributed to the base rate, except for the oral-only renal dialysis drugs where payment under the ESRD PPS has been delayed. In the CY 2016 ESRD PPS proposed rule (80 FR 37832), we reiterated that we grouped the injectable and intravenous drugs and biologicals by action, or more specifically, into functional categories for the purpose of adding new drugs or biologicals with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. We

also stated that in past rules we referred to these categories as *drug categories* but we believe the term *functional categories* is more precise and better reflects how we have used the categories. We discuss the proposal and the finalized definition of this term in 42 CFR 413.234(a) later in this discussion.

In the proposed rule (80 FR 37833), we explained that since the ESRD PPS CY 2011 final rule was published, the base rate has been updated by the ESRDB market basket, discussed in section II.B.2. of this final rule, which reflects changes in the drug price indices. In addition, we stated that we designated several new drugs and biologicals as renal dialysis services because they fit within the functional categories captured in the base rate and no adjustment to the base rate has been made, consistent with the CY 2011 ESRD PPS final rule. We proposed that this approach of considering drugs and biologicals as included in the ESRD PPS base rate if they fit within one of our functional categories would continue as part of the drug designation process described below.

b. Final Drug Designation Process

i. Inclusion of New Injectable and Intravenous Products in the ESRD PPS Bundled Payment

In the CY 2016 ESRD PPS proposed rule (80 FR 37831), in accordance with section 217(c)(2) of PAMA, we proposed to include new injectable and intravenous products in the ESRD PPS bundled payment by first determining whether the new injectable or intravenous products are reflected currently in the ESRD PPS. We proposed to make this determination by assessing whether the product can be used to treat or manage a condition for which there is an ESRD PPS functional category. We stated that under our proposed regulation at 42 CFR 413.234(b)(1), if the new injectable or intravenous product can be used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or intravenous product would be considered reflected in the ESRD PPS bundled payment and no separate payment would be available. Specifically, any new drug, biosimilar, or biologic that fits into one of the ESRD functional categories would be considered to be included in the ESRD PPS. We stated that these drugs and biologicals would count toward the calculation of an outlier payment. In the calculation of the outlier payment, we price drugs using the ASP pricing methodology, which is generally ASP+6 percent. We believe that this step in our process codifies in regulation our existing policy of using the functional categories to add drugs to the bundled payment, which we finalized in the CY 2011 ESRD PPS final rule (75 FR 49047 through 49052).

Also, we proposed that if the new injectable or intravenous product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or intravenous product would not be considered included in the ESRD PPS bundled payment, and we proposed to take the following steps as described in our proposed regulation at § 413.234(b)(2): (i) Revise an existing ESRD PPS functional category or add a new ESRD PPS functional category for the condition that the new injectable or intravenous product is used to treat or manage; (ii) pay for the new injectable or intravenous product using the transitional drug add-on payment adjustment discussed below; and (iii) add the new injectable or intravenous product to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

For purposes of the drug designation process, we proposed to define a new injectable or intravenous product in our regulation at § 413.234(a) as an injectable or intravenous product that is approved by the Food and Drug Administration (FDA) under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, assigned a Healthcare Common Procedure Coding System (HCPCS) code, and designated by CMS as a renal dialysis service under § 413.171. In the proposed rule (80 FR 37832), we explained that following FDA approval, injectable or intravenous drugs then go through a process to establish a billing code, specifically a HCPCS code. Information regarding the HCPCS process is available on the CMS Web site at *https://www.cms.gov/medicare/coding/MedHCPCSGenInfo/Application_Form_and_Instructions.html*. We stated that we would designate injectable and intravenous products as renal dialysis services under the ESRD PPS by analyzing the information in the FDA-approved labeling, the HCPCS application information, including studies submitted as part of these two standardized processes. We indicated that a change request would be issued that will provide notice that the drug is included in the ESRD PPS bundle and is available for use, allowing patients to have access to the new drug.

We proposed to codify the term ESRD PPS functional category at § 413.234(a) as a distinct grouping of drugs and biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. We explained that we would codify this definition in regulation text to formalize the approach we adopted in CY 2011 because the drug designation process is dependent on the functional categories. In the proposed rule (80 FR 37832), we listed the 11 functional categories that are used to treat or manage conditions associated with ESRD, which are displayed in Table 8A below.

TABLE 8A—ESRD PPS FUNCTIONAL CATEGORIES

Category	Rationale for association
Access Management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Bone and Mineral Metabolism	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.
Cellular Management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
Antiemetic	Used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple clinical indications and are included for their action to treat itching secondary to dialysis.

TABLE 8A—ESRD PPS FUNCTIONAL CATEGORIES—Continued

Category	Rationale for association
Anxiolytic	Drugs in this classification have multiple actions but are included for the treatment of restless leg syndrome secondary to dialysis.
Excess Fluid Management	Drug/fluids used to treat fluid excess/overload.
Fluid and Electrolyte Management Including Volume Expanders.	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs used to treat graft site pain and to treat pain medication overdose.

We proposed to determine whether a new injectable or intravenous product falls into one of our existing functional categories by assessing whether the product is used to treat or manage the condition for which we have created a category. We believe that this approach to determining whether a new drug falls into one of our existing drug categories is consistent with the policy we finalized in the CY 2011 ESRD PPS final rule (75 FR 49047 through 49052).

The comments we received and our responses are below.

Comment: A national organization of dialysis organizations, an organization of kidney care providers, manufacturers, and patient advocates, and an LDO commented that CMS does not have the statutory authority to add new renal dialysis services to the ESRD PPS bundle. The commenters believe that section 217(c) of PAMA only permits CMS to develop a process for adding new drugs to the bundle, which they contend is fundamentally different than permitting CMS to actually add new drugs to the bundle. One commenter stated that, in contradicting the plain meaning of section 217(c)(2) of PAMA, the proposed rule renders it meaningless.

One commenter asserted that section 217(c)(2) of PAMA cannot be read in isolation of section 1881(b)(14)(B) of the Act as the sole authority to add new drugs to the bundle; rather, section 217(c)(2) must be read in concert with section 1881(b)(14)(B), which does not permit new injectable or intravenous drugs to be added to the bundle. Other commenters stated that CMS seems to assume, incorrectly, that the existing statutory definition of renal dialysis services can accommodate new injectable or intravenous drugs. A number of commenters echoed this contention, asserting that the text, structure, and purpose of section 1881(b)(14)(B) of the Act show clear congressional intent not to allow CMS to add new injectable or intravenous drugs into any of the four articulated categories of renal dialysis services. The commenters explained that PAMA did not amend the definition of renal dialysis services in section 1881(b)(14)(B) of the Act, and therefore CMS is not authorized to add new ESRD drugs to the ESRD PPS bundled payment. Specifically, section 1881(b)(14)(B)(i) includes only items and services being paid for under the previous composite rate payment system as of December 31, 2010. They further explained that section 1881(b)(14)(B)(ii) refers only to ESAs and any oral form of ESAs furnished for ESRD treatment, and the plain language of this provision excludes non-ESAs. With respect to section 1881(b)(14)(B)(iii), the commenters stated that this category excludes new injectable or intravenous drugs because, even if a new injectable or intravenous drug is being furnished to individuals for the treatment of ESRD, it would not have been separately paid for under the Act prior to January 1, 2011, and therefore, for CMS to read section 1881(b)(14)(B)(iv) as allowing the addition of new injectable or intravenous products to the bundle, renders category (iii) meaningless. Some commenters stated that section 1881(b)(14)(B) of the Act is clear and unambiguous. Another commenter stated that the proposed process violates step one under *Chevron* v. *NRDC,* 467 U.S. 837 (1984) because the statute's language is clear and unambiguous.

Response: We believe we have the authority to add new renal dialysis services to the bundle under both sections 1881(b)(14)(B) of the Act and 217(c)(2) of PAMA. First, we read section 1881(b)(14)(B)(iii) as requiring the inclusion of a specific category of drugs in the bundle—that is, drugs and biologicals, including those with only an oral form, furnished to individuals for the treatment of ESRD and for which separate payment was made prior to January 1, 2011. We also read section 1881(b)(14)(B)(iv) as specifying a different category of items that must be included in the bundle—that is, items and services, which includes drugs and biologicals, not specified by sections 1881(b)(14)(B)(i), (ii), or (iii). Second, we read the language of section 217(c)(2) of PAMA—''the Secretary of Health and Human Services . . . shall establish a process for . . . including new injectable and intravenous products into the bundled payment system''—as more than a directive to simply develop an inoperative scheme. We believe the provision requires us to both define and implement a drug designation process for including new injectable and intravenous products into the bundle.

Comment: As several commenters noted that the Administrative Procedure Act (APA) precludes CMS from assuming that new injectable or intravenous drugs can constitute renal dialysis services because the application of that assumption constitutes CMS adopting a policy without going through notice- and -comment rulemaking. Several commenters further indicated that all new drugs should be added to the bundle only through notice-and-comment rulemaking. Specifically, when CMS is determining that a drug or biological (whether it is substantially the same as a drug or biological currently in the bundle or not) should be added to the bundle, all data should be presented and the process should be complete and transparent to allow interested stakeholders to evaluate the proposals before they are finalized. While they acknowledge that there would be a gap between launch of the new product and publication of a proposed and final rule, they strongly recommend that CMS use an interim rulemaking process or guidance to allow the product to be paid for separately outside the bundle until the rulemaking process can be completed. They do not believe such substantive changes in policy and payment rates should be adopted through sub-regulatory guidance. Other commenters pointed out that the proposed rule does not specify any public process for adding a new drug to an existing category or creating a new category, which is problematic given that serious APA concerns are raised if a regulated party is not given an opportunity to comment on a policy that affects settled legal rights.

A national dialysis organization strongly urged CMS to adopt the same process for all new drugs and biologicals unless they are substantially

the same as drugs or biologicals currently paid for under the ESRD PPS payment rate. For new drugs or biologicals that are substantially the same as drugs or biologicals currently paid under the ESRD PPS, the organization supported incorporating them into the PPS on a case-by-case basis using notice-and-comment rulemaking and foregoing the transition period if it can be shown that the PPS rate is adequate to cover the cost of the drug or biological. If the rate is inadequate to cover the cost of the new drug, the transitional drug add-on payment adjustment should apply.

Finally, another commenter stated that the proposed rule does not specify any public process for adding a new drug to an existing category or creating a new category, which the commenter believes raises serious APA concerns. They urged CMS to utilize notice-and-comment rulemaking to add new drugs to the ESRD PPS.

Response: As stated above, the functional categories and our process for adding new drugs to the bundled payment when they fit into those functional categories was adopted in response to public comments in the CY 2011 ESRD PPS final rule and has been our policy since the inception of the ESRD PPS. We've added new drugs to the ESRD PPS bundled payment consistent with this policy in the years since the ESRD PPS was implemented and announced those additions using change requests. These decisions have not been controversial because the drugs were substantially the same as other drugs in the functional category. However, in response to commenters' request for the opportunity to provide input for determinations in the future that may be controversial, we will consider in future rulemaking establishing an informal process for obtaining public input when new injectable or intravenous products are added to an existing functional category.

We do not believe it is necessary to add injectable and intravenous products to the bundled payment using notice-and-comment rulemaking because we have already included dollars in the base rate to account for products used to treat or manage conditions associated with ESRD for which we have adopted functional categories—consistent with the process we adopted through notice-and-comment rulemaking—and we believe that new drugs used to treat or manage the same conditions will be adequately accounted for by those categories. We also believe that our process of reviewing the FDA labeling data and information, reviewing the information presented for obtaining a HCPCS code, and CMS internal medical review following the announcement of the FDA and HCPCS decision, allows new drugs to be added to the bundled payment as quickly as possible, whereas subjecting these additions to notice-and-comment rulemaking would significantly delay inclusion of new drugs in the PPS, even though there are already dollars in the base rate to account for those products and the process for adding these products to the bundle has been in place since 2011. For new renal dialysis service drugs or biologicals that do not fit within one of our existing categories, however, we will revise or adopt a new functional category, pay a transitional add-on payment adjustment for the new product, and make any necessary changes to the base rate to account for the new product, and all of those steps will be subject to notice-and-comment rulemaking.

Comment: An LDO objected to the proposed definition of functional category as a distinct grouping of drugs and biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. They believe the definition expands the statutory definition of renal dialysis services by implying that the categories now may include any drugs associated with ESRD, without regard to whether those drugs are actually essential to the delivery of maintenance dialysis. A national dialysis organization requested that CMS affirmatively state that the bundled drugs must be renal dialysis services for the treatment of ESRD and connected to/contemporaneous with the dialysis procedure. The commenters suggested changes to the descriptions of some of the functional categories to more precisely define the drugs that would fit into the categories. In particular, the commenters suggested changes to the anti-infective, pain management, and anxiolytic functional categories to better describe how each of the categories relate to the treatment of ESRD in accordance with the statute. The organization suggested that language be removed from the description of the antiemetic functional category to eliminate drugs used to treat nausea caused by the use of oral-only drugs because these drugs are paid outside the bundle and are covered under a separate benefit category.

An organization of home dialysis patients also requested that CMS put a policy in place to ensure that the drugs included in the bundle relate to dialysis care only and not overall care. The commenter gave the example of when oral-only transplant medications would be added to the bundle. They noted that some patients need to stay on their transplant medications even when the kidney no longer functions well because the drugs help prevent rejection of the kidney and the increase of more antibodies. The commenter stated that they understand the need to control costs, but they believed the proposed drug designation process was excessive and could hinder innovation and prevent new treatment options from entering the marketplace.

Response: We did not intend to expand the functional categories beyond the drugs and biologicals used in the treatment of ESRD, and we do not believe our definition of ESRD PPS functional category in the regulations at 42 CFR 413.234 does that. With regard to limiting renal dialysis services to those that are essential to the delivery of maintenance dialysis, we note that we believe the drugs that are and will be included in the ESRD PPS bundled payment are limited to those that are essential to the delivery of maintenance dialysis. In particular, we believe all drugs that fit into our existing functional categories (which have been revised slightly as described below) are essential to the delivery of maintenance dialysis because they are necessary to treat or manage conditions associated with the beneficiary's ESRD, and thus, they enable the beneficiary to remain sufficiently healthy to continue receiving maintenance dialysis.

With regard to the concern about bundling oral-only transplant medications into the ESRD PPS, we note that immunosuppressive drugs are covered under Part B under a separate benefit category and those drugs do not fit into the functional categories under the ESRD PPS.

Regarding the commenter's concerns about overly broad definitions for the anti-infective, pain management, and anxiolytic categories, we note that we moved the anti-infective functional group from the always used for the treatment of ESRD list to the may be used for the treatment of ESRD list for precisely the reasons given by the commenter. We recognize that there could be medical situations in which the beneficiary requires an anti-infective that has nothing to do with ESRD and access site infections or peritonitis. Therefore, when ESRD facilities furnish drugs or biologicals that are identified on Table 8B as those that may be used for the treatment of ESRD (for example, the pain management and anxiolytic functional categories) for reasons other than the treatment of ESRD, they can receive separate payment for the drug when it is reported with the AY

modifier on the claim. Appending the AY modifier to the line item drug or biological on the claim is an attestation that the item or service is not being furnished for the treatment of ESRD.

We have carefully reviewed the commenters' recommendations regarding narrowing the functional categories to describe how the category relates to the treatment of ESRD. Many of the commenters' recommendations are consistent with how we believe the categories should be defined and help to ensure that the drugs that fall into them are those that are essential for the delivery of maintenance dialysis. Therefore, we are adopting several of them. The final functional categories as revised with suggestions from commenters are included in Table 8B, with the commenters' suggestions italicized.

TABLE 8B—ESRD PPS FUNCTIONAL CATEGORIES

Category	Rationale for association
DRUGS ALWAYS CONSIDERED USED FOR THE TREATMENT OF ESRD	
Access Management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Bone and Mineral Metabolism	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.
Cellular Management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
DRUGS THAT MAY BE USED FOR THE TREATMENT OF ESRD	
Antiemetic	Used to prevent or treat nausea and vomiting *related to* dialysis. Excludes antiemetics *used for purposes unrelated to dialysis, such as those* used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat *vascular access-related and peritonitis* infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple clinical indications. *Use within an ESRD functional category* includes treatment for itching *related to* dialysis.
Anxiolytic	Drugs in this classification have multiple actions. *Use within an ESRD functional category* include treatment of restless leg syndrome *related to* dialysis.
Excess Fluid Management	Drug/fluids used to treat fluid excess/overload.
Fluid and Electrolyte Management Including Volume Expanders.	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs used to treat *vascular access* site pain and to treat pain medication overdose, *when the overdose is related to medication provided to treat vascular access site pain.*

We did not incorporate the commenters' recommended language that would remove from the antiemetic functional category drugs used to treat nausea resulting from oral-only drugs that are currently paid for outside the bundle. The commenter's rationale was that the oral-only drugs are covered under a separate benefit category. We believe, however, that if the oral-only drugs are being given for the treatment of ESRD and they cause nausea, then the drug used for treatment of that nausea falls within the antiemetic functional group covered by the ESRD PPS. Specifically, if drugs are used to treat nausea caused by the oral-only drugs designated as renal dialysis services (calcimimetics and phosphate binders), then the drug used for the treatment of the nausea falls within the functional group covered by the ESRD PPS. However, when other Part D oral-only drugs are prescribed to treat non-ESRD conditions and those drugs cause nausea, then the drugs used to treat the nausea would also be separately covered.

Finally, with respect to the comment that the drug designation process would hinder innovation, we note that for novel drugs that are used to treat or manage a condition for which we do not have a functional category, we will revise an existing category or adopt a new category to cover the drug and pay a transitional drug add-on payment adjustment for at least 2 years. For drugs that are used to treat or manage a condition for which we have a functional category, we note that we have not encountered high cost drugs that we believe would not be accounted for by the existing functional categories. We do, however, appreciate the commenters' concerns and we anticipate addressing the possibility of the unique situations they have identified in future rulemaking.

Comment: One national dialysis organization stated that adding new drugs or biologicals to existing functional categories presumes that CMS can exercise clinical judgment as to what drugs will be related to the treatment of ESRD before the majority of clinical professionals have had the opportunity to use them.

Response: We define a new injectable or intravenous product in our regulation at § 413.234(a) as an injectable or intravenous product that is approved by the FDA under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, assigned a Healthcare Common Procedure Coding System (HCPCS) code, and designated by CMS as a renal dialysis service under § 413.171. In the proposed rule (80 FR 37832), we explained that following the clinical trials intended to support FDA approval, and after FDA approves the drugs for use in ESRD patients, injectable or intravenous drugs then go through a process to establish a billing code, that is, the HCPCS code process. The HCPCS process involves the input of physicians and stakeholders. Additionally, if a drug will be used for both the treatment of ESRD and for the treatment of non-ESRD conditions, it would receive two HCPCS codes. We stated that we would designate

injectable and intravenous products as renal dialysis services under the ESRD PPS by analyzing the information in the FDA-approved labeling, the HCPCS application information, and a review by CMS medical officers and medical personnel, in addition to reviewing clinical studies submitted. In all three of these steps, physicians assist in the determination as to whether a new drug is a renal dialysis service as well as whether the new drug fits into one of the functional categories. We believe the information provided for the FDA approval, HCPCS coding process, and the CMS internal review by medical professionals will provide sufficient information over a period of time for CMS to determine the following: (1) Whether a product is a new injectable or intravenous drug; (2) whether the drug is a renal dialysis service; and (3) whether the drug fits into an existing functional category. If a new drug is not considered to be a renal dialysis service, then it will not be a part of the ESRD PPS bundle.

Comment: One professional association suggested that when new agents are newly introduced and have a role either similar to or identical to existing agents and are not associated with better outcomes, they should be included in the current PPS without additional payment.

Response: We agree with the commenter's suggestion for adding new drugs whose role is either similar or identical to existing agents to the existing functional categories. We believe that the drug designation process finalized at 42 CFR 413.234 addresses the commenter's concern.

Comment: A large dialysis organization commented that the proposal does not conform to the PAMA directive to establish a process for including new injectable and intravenous products into the ESRD PPS bundled payment, but instead established a regulatory process for including only new functional categories of drugs within the ESRD PPS bundled payment. Only if a new drug also represents a new *functional category* would the proposed transitional drug add-on payment adjustment apply. The organization believes the proposed rule requires an extremely broad notion of functional categories of drugs included in the ESRD PPS that expands the ESRD PPS in a manner outside of the statutory construct. With respect to the process for including new injectable or intravenous drugs into the PPS and the use of the functional categories of ESRD drugs and biologicals, commenters expressed concern about the overly broad definitions of the functional categories and the proposal to categorize injectable and intravenous drugs and biologicals as within the bundle if they seem to fit into one of the functional categories. The commenters stated that it is even more concerning that new categories will be added if the current broadly-defined categories do not incorporate new injectable or intravenous drugs or biologicals. The organization believes that these policy choices would result in no such drug or biological being defined as new, which is inconsistent with the congressional interest in establishing a process for including new injectable and intravenous products into the bundled payment.

A dialysis organization and a professional association asked that CMS consider a pass-through payment for all new drugs that are considered truly new. They recommend a rate of 106 percent of ASP, minus the portion of the ESRD PPS base rate that CMS determines is attributable to the category of drugs that corresponds to a truly new drug.

Response: In accordance with section 217(c) of PAMA, we proposed a process that would allow us to include new injectable and intravenous products into the ESRD PPS bundled payment, and, when appropriate, to modify the ESRD PPS payment amount to reflect the costs of furnishing a new injectable or intravenous renal dialysis service drug or biological that is not bundled in the ESRD PPS payment amount. We believe the proposal conforms to the PAMA directive to establish a process for including new injectable and intravenous products into the ESRD PPS bundled payment. The commenter seems to be concerned not with the process of adding new drugs to existing functional categories as described in the CY 2011 final rule, but with payment of those new injectable and intravenous drugs that fit into the functional categories. As indicated in the CY 2011 final rule, the current ESRD PPS has dollars built into the base rate for drugs within the functional categories. If a new drug is available, a determination is made as to whether it is a renal dialysis service drug. This is determined through reviewing the publicly-available data and information underlying the FDA approval process, approved labeling, and the information provided during the HCPCS review process and following an internal CMS medical review process. Next, a determination is made as to whether the drug fits into one of the functional categories. The proposed transitional drug add-on payment adjustment is only made for new injectable and intravenous drugs used for the treatment of ESRD for which there is no current functional category because we've included dollars in the base rate to account for drugs used to treat or manage conditions associated with ESRD for which we have a functional category. However, as there is nothing in the base rate to account for drugs in a new functional group, those drugs would be paid using the pricing methodologies specified under section 1847A of the Act (which could include ASP + 6 percent) for a minimum of 2 years. With respect to the commenters' concern that the functional categories are too broad, we note that we adopted several of the commenters' suggested changes to the descriptions of the functional categories above.

Comment: An LDO and a drug manufacturer stated that the ESRD statute requires budget neutrality apply only in 2011; they do not believe the Congress intended for CMS to add new items or services to the bundle without increasing the overall Medicare spending for ESRD. In other words, the Congress has not required CMS to reduce spending on currently bundled items and services when it adds new items or services to the bundle. A national dialysis organization indicated that CMS must ensure that limited conceptual views of budget neutrality will not jeopardize good policy decisions and ensure that reimbursement resources are adequate to provide necessary products and services to beneficiaries.

Response: We agree with the commenter with respect to new drugs that do not fit within one of the functional categories. Where appropriate, dollars will be added to the base rate to account for those drugs that fall within the new functional categories and this would increase ESRD expenditures. However, for drugs that are used to treat or manage conditions associated with ESRD for which we have existing functional categories, we do not believe it would be appropriate to increase Medicare expenditures by providing additional payment beyond the ESRD PPS base rate. We note that the ESRD bundled (ESRDB) market basket updates the PPS base rate annually for input price changes for providing renal dialysis services as specified by the bundle. The ESRDB market basket update accounts for price changes of the drugs and biologicals that are reflected in the ESRD PPS base rate. For example, the market basket includes price indices, published by the Bureau of Labor Statistics, such as the PPI Biological Products for Human Use and

the PPI Vitamin, Nutrient, and Hematinic Preparations. The ESRDB market basket is discussed in section II.B.2 of this final rule and the cost weight and price proxies are discussed in detail in the CY 2015 final rule 79 FR 66129 through 66133. We appreciate the commenters' concerns regarding the cost of new drugs that fall within the existing functional categories and we anticipate addressing the possibility of the unique situations they have identified in future rulemaking.

Comment: For new drugs, one organization proposes a different process adapted largely from the hospital OPPS mechanism for incorporating new drugs into its ambulatory payment classification (APC) system, which is a reasonable and known method to incorporate new drugs into an existing PPS. The OPPS mechanism provides additional payment (pass-through payment) for a limited time period (2 to 3 years) to account for the cost of new drugs before the cost is able to be fully reflected in the applicable APC. Two drug industry groups and three drug manufacturers commented that the proposed eligibility criteria for obtaining the transitional drug add-on payment are overly restrictive and will prevent this policy from motivating the provision of high-quality, efficient, and effective care. They agree that we should decouple the transitional drug add-on from the functional categories and provide the additional payment for all new injectable and intravenous drugs and biologicals and oral equivalents for 2 to 3 years, similar to the IPPS or the OPPS. A professional association recommends that when a new product for dialysis care becomes available, new money should be allocated to pay for the new product.

One of the drug manufacturers believes that these new renal dialysis service drugs should meet similar newness criteria as those that CMS applies in the IPPS for the New Technology Add-On Payment. Under that program, a specific medical service or technology is considered new for purposes of new technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology and the system is recalibrated.

Response: If a new drug is determined to be a renal dialysis service and it does not fit into a current functional category, then no dollars have been included in the base rate for the functional category. A new functional category will be proposed through notice-and-comment rulemaking and the drug will be paid for using a transitional drug-add on payment adjustment for at least 2 years while utilization data are collected. We understand the commenters' recommendation that CMS should make pass-through payments for all new drugs, including both those that fit into current functional groups and those that do not in a manner similar to the OPPS pass-through payments process. We note that while the OPPS pass-through policy provides additional payment for new drugs, those payments are made in a budget-neutral manner. If we were to provide additional payment for new drugs that fit into an existing functional category, we would similarly want to make such a policy budget-neutral because we have already accounted for those drugs in the PPS base rate. We believe our process is preferable because it would not involve reducing the base rate to fund additional payments for new drugs that fit into an existing functional category.

Under the new technology add-on payment (NTAP) policy, additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. Importantly, not all new technologies or medical services for which an application is submitted to CMS are determined to be eligible for the NTAP.

We believe the drug designation process will allow us to pay the transitional drug add-on payment adjustment for more new products than if we utilized a policy similar to the NTAP. This is because under our drug designation process, all new injectable and intravenous renal dialysis service products that do not fit into an existing functional category will be paid for using the transitional drug add-on payment adjustment for a minimum of 2 years and the products will not need to meet clinical improvement or cost criteria. In addition, the transitional drug add-on payment adjustment is calculated using the pricing methodologies specified in section 1847A of the Act. We believe payment for these drugs using those pricing methodologies will capture the cost of expensive new injectable or intravenous products and be consistent with how drugs and biologicals are paid under Part B.

Comment: A large dialysis organization stated that defining new drugs requires special consideration of cost. They suggested that rather than comparing the cost of the new drug to the ESRD PPS base rate, we should compare it to the cost of the existing drugs in the same CMS-defined ''mode of action'' category. In such a case, a drug might qualify for payment of the transitional drug add-on payment adjustment on the basis that its cost per unit or dosage exceeds a specified percentage (for example 150 percent) of the average cost per unit or dosage of the top three most common drugs in the same category (based on utilization data). This comparison would demonstrate that the amount allocated to that category in the ESRD PPS base rate is insufficient to cover the cost of the new drug. An LDO stated that by failing to account for the costs of new drugs that enter the market, the proposed rule represents a severe departure from the fundamental cost basis of the ESRD PPS. An organization representing small and medium dialysis facilities and an MDO expressed concern that many drugs would be automatically included in the bundle without any evaluation of the drug's cost or whether it should be considered the standard of care for dialysis patients.

A drug manufacturer believes the transitional drug add-on payment adjustment should apply to all new drugs and, in particular, drugs designated as priorities by the FDA under the Generating Antibiotics Incentives Now (GAIN) Act or the Qualified Infectious Disease Product (QIDP) Act, not just those drugs that are used to treat or manage a condition for which we have not adopted a functional category, in order to promote access to new therapies and encourage innovation in ESRD care. They pointed out that the functional categories are very comprehensive and capture every known condition related to ESRD. They indicated that under the proposed approach CMS would make no additional payment regardless of whether the drug has a novel mechanism of action, new FDA approval, or other distinguishing characteristics. The commenter believes the CMS proposal sends conflicting messages to manufacturers about the importance of developing new treatments for this underserved patient population.

An organization of nonprofit SDOs commented that CMS should provide additional payment for drugs and biologicals that would fall within an existing functional category that represent a significant clinical improvement and may warrant a higher payment. The commenter noted that utilizing the outlier policy to address

these high costs ultimately comes at the expense of the bundled base rate and would not cover the full cost of the new drug or biologic.

Response: We appreciate the commenters' suggestion to compare the cost of new drugs to the cost of existing drugs in the same functional categories and to utilize the transitional drug add-on payment adjustment for all new drugs. Our intent in adopting the functional categories in the CY 2011 ESRD PPS final rule was to be as comprehensive as possible with regard to the drugs used in the treatment of ESRD at the time the rule was written. We are concerned that comparing the cost of new drugs and biologicals to the existing drugs in a category would impact drug manufacturers' drug pricing strategy and marketing and lead to higher prices for all new drugs. Because our intent is to better align ESRD PPS payment with resource utilization, including the utilization of new drugs that would fit into the current functional groups and those that would fit into a new functional category, we will consider in future rulemaking how to address these unique situations. The commenters' suggestions, including a review of the drugs designated as priorities by the FDA under the Generating Antibiotics Incentives Now (GAIN) Act or the Qualified Infectious Disease Product (QIDP) Act, are the type of input we would seek from stakeholders if such a process were to be implemented. In future rulemaking, we plan to address these unique situations by considering ESRD facility resource use, supporting novel therapies for ESRD patients, and balancing the risk of including new drugs for both CMS and the dialysis facilities.

We agree with the commenter who noted that while the outlier policy was included to mitigate the risk of high-cost patients, by design, it would not cover the full cost of a new drug or biologic because outlier payments are made only for costs above the fixed dollar loss ratio. In response to the concern that drugs would be automatically included in the bundle without any evaluation of whether they should be included in a dialysis patient's standard of care, we note that a new drug that would potentially be considered a renal dialysis service drug would only be included in a current functional category if the FDA indicated the drug was for treatment of ESRD patients, it obtained a HCPCS code, and a review performed by CMS medical officers and subject matter experts confirms that the new drug is a renal dialysis service and covered under a current functional category. This review will take into account reports of efficacy, adverse events and utilization patterns. Also, we note that the inclusion of a new drug in the ESRD PPS bundled payment does not require that it be prescribed to a particular beneficiary. Rather, the patient and their nephrologist should determine the patient's plan of care.

With regard to the comment that CMS would make no additional payment in the future for any new drugs, we do not believe this will be the case. Since publication of the CY 2011 ESRD PPS final rule, CMS has been introduced to novel therapies and drugs that are under development that would require new functional categories. As a result, the drug designation process was designed to address potential new therapies that would necessitate additional payment, at least temporarily in the form of a transitional drug add-on payment adjustment, and perhaps permanently in the form of a change to the base rate.

Comment: A national dialysis organization with the support of other dialysis organizations provided an example of the process they are recommending using with an anti-infective as the new drug in the example. The commenter indicated that the determinations in each step of the process would be made through notice-and-comment rulemaking with CMS providing sufficient data to allow interested stakeholders to fully evaluate the proposals.

Step 1: Determine if the injectable or intravenous drug/biological is substantially the same as a drug/biological that is related to the treatment of ESRD and currently within the ESRD PPS. In the example provided, the anti-infective would likely be used to treat vascular access-related infections. If the anti-infective is substantially the same as drugs currently used to treat infections related to a patient's catheter (for example), then it would be added to the bundle. If, however, the ESRD PPS rate is likely insufficient to cover the cost of providing the drug it should be evaluated through a transition period.

Step 2: Determine the utilization and cost of the injectable and intravenous drug/biological before incorporating it into the bundle. In the example, if the new anti-infective is not substantially the same as an existing drug in the bundle, CMS would establish a 2–3 year transition period during which facilities would be paid separately for the drug at ASP+6 percent under Part B and not as an ESRD service.

Step 3: Determine if the injectable and intravenous drug/biological is a renal dialysis service. Based upon the information collected during the transition period, CMS through notice-and-comment rulemaking would determine whether the item is a renal dialysis service. If so, CMS would value the Part B and beneficiary costs of the item (determined at the time the item is added to the bundle) and add that amount to the base rate without applying the budget neutrality construct.

Another drug manufacturer commented that CMS did not provide enough information about how the cost for new drugs would be incorporated. Several commenters similarly commented that when trying to determine whether an injectable or intravenous drug or biological should be added to the bundle, CMS will need to determine whether it is substantially the same as other drugs or biologicals currently in the bundle. Commenters supported incorporating new drugs or biologicals that are substantially the same as drugs or biologicals currently paid under the ESRD PPS into the bundled payment on a case-by-case basis, foregoing the transition period if it can be shown that the PPS base rate is adequate to cover the cost of the drug or biological. However, commenters stated that if the rate is inadequate to cover the cost of the new drug, the transitional drug add-on payment adjustment should apply to the PPS payment. Commenters noted that it would not be appropriate to add such drugs and biologicals to the bundle without first learning about their utilization patterns or costs and without adjusting the payment rate in a non-budget-neutral manner.

A national dialysis patient advocacy organization explained that if new products are immediately added to the bundle without additional payment it would curtail innovation in treatments for people on dialysis. They believe clinicians should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes and that the proposed rule did not allow for this. The commenter explained that Kidney Disease Improving Global Outcomes (KDIGO) and Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines are often updated when evidence of improved therapies on patient outcomes are made available and that this rigorous and evidence-based process is extremely important in guiding widespread treatment decisions in nephrology. The commenter expressed concern that under the proposed rule, reimbursement and contracting arrangements could instead dictate utilization of a product before real world evidence on patient outcomes is ever generated.

Response: We appreciate the commenters' input into the process of determining whether a drug is a renal dialysis service, and if so, whether it fits into one of the current functional categories. The focus of the commenter's suggested three steps seems to be on payment, with the determination of whether a new drug warrants additional payment depending on a determination of whether a new drug is *substantially the same* as an existing drug. It is unclear to us, however, whether *substantially the same* means that the new drug has been classified as a generic for an existing drug; that it acts on the same biochemical pathways as a drug currently in the bundle; that there is the same interaction of the drug with its receptors at a molecular level as a drug in the category; or that the new drug does not cost *substantially the same* as another drug currently in the category. It is unclear what the commenter means when they use the phrase *substantially the same* to describe a new drug. Nonetheless, we believe the process we proposed is preferable to processes that would use any of the possible *substantially the same* scenarios described above because we already have dollars in the base rate for drugs in the current functional categories. As we stated previously, we believe that if we adopted the commenter's recommendation, we would encourage over-pricing of all new intravenous and injectable drugs. The current functional categories include drugs that have demonstrated efficacy as renal dialysis services in the treatment of ESRD. As CMS does not dictate utilization of a drug, the addition of new drugs and biologics to the functional groups is to provide choice to the dialysis suppliers and availability of new products to the beneficiaries. We will monitor changes in utilization of those new drugs by the medical community. Inclusion of a drug in the bundle does not require that nephrologists prescribe it.

If the drug does not fall within one of the functional categories, then a determination will be made as to whether the drug is a renal dialysis service, and a new functional category will be proposed through notice-and-comment rulemaking. A transitional drug add-on payment will be made for a minimum of 2 years. During that time utilization data will be gathered. At the end of that time, the drug will be included within its new functional category and the base rate may or may not be modified to account for the cost of the drug, depending upon what the utilization data show.

With respect to what seem to be commenters' specific concerns that certain high cost new drugs may not be adequately accounted for in the ESRD PPS base rate, we note that we anticipate making further proposals related to the drug designation process to address these unique situations in future rulemaking.

Comment: A national dialysis organization stated that the market basket is an inflationary, not a reimbursement, mechanism. They expressed concern that adjustments to the market basket may have significant time lag between product approval and inclusion in the market basket. They further explained that categories of drug entrants may not match the current price proxies utilized in the ESRD PPS, requiring future revaluation.

Response: The market basket adjusts payments for inflation on a yearly basis. We agree that there may be a lag between costs for items included in the ESRDB market basket cost weights and costs for newly added or excluded expenses in the ESRD treatment bundle. We note that any CMS PPS payment, updated by a market basket, faces the same potential lag. The data used to construct cost weights for the ESRD providers is based on Medicare Cost Reports which are only available with a lag. Additionally, CMS has found that the cost weights for a market basket do not change significantly from year to year. As we have in the past, we will continue to evaluate the ESRD cost share weights on a regular basis and propose changes to the market basket should data indicate a substantial shift in relative cost weights in providing ESRD bundled services.

Comment: An organization of home dialysis patients commented that the functional categories defined for dialysis medication are too broad and could prevent people on dialysis from receiving needed care and be detrimental to innovation. The commenter stated that in the future there could be a new medication to help with fluid management but patients would be shut out of ever having the option for a new fluid management therapy. An LDO stated that, if implemented, the proposed process could jeopardize patient access to drugs that are clinically superior to existing drugs in the same functional category.

An organization of home dialysis patients is hopeful that there are a number of therapies that will offer choice and better care to people who have an illness. One new area of care is in the form of biologics. In order to incentivize new medications to come to market, the home dialysis patient organization asked that CMS provide additional payment for new drugs that fit into the functional categories in order to incentivize new medications to come to market and to ensure they have the opportunity for better care, choices and treatment.

Response: There seem to be two concerns expressed by the commenters. The first is that the broad nature of the functional categories will sweep new drugs into the functional categories and beneficiaries will not have access to the drugs because the dialysis organizations will choose not to use the new drugs, whether because of contractual obligations, affiliation with drug manufacturers, or lack of additional dollars in the base rate. The second concern seems to stem from the first in that the organizations will not use the new drugs because they would not be separately paid for using the new drugs. Therefore, ESRD patients will not have access to the new drugs.

To address the first issue, the primary intent of the proposed approach is to provide timely patient access to new drugs for the treatment of ESRD. This includes availability of both new drugs that fit into an existing functional category and drugs for which there is no current functional category. The second issue is a matter of reimbursement. As indicated in the CY 2011 final rule, the current ESRD PPS has dollars built into the base rate for the drugs in the functional categories. After a new drug is approved by the FDA and assigned a HCPCS code, CMS makes a determination as to whether it is a renal dialysis drug. If we determine that the drug is a renal dialysis service drug, then we are not permitted to pay for the drug outside the ESRD PPS bundle.

We appreciate the concerns expressed by the organization of home dialysis patients regarding biologics. The biologics currently included in the ESRD PPS bundled payment are ESAs, which are defined as renal dialysis services in section 1881(b)(14)(B)(ii) of the Act. When a new biologic other than an ESA becomes available, we will treat it as we do any other new drug. Specifically, we will evaluate whether it is a renal dialysis service and if it is, whether it fits into a current functional category.

In response to stakeholder concerns regarding the availability and increased cost of new drugs, we recognize that newer drugs may be more costly; however, the new drug may replace the functional use of one or more drugs within one or several functional categories. Nonetheless, we understand commenters' concerns about the potential cost of new drugs that fall into

existing categories and we will consider these unique situations in future rulemaking.

Comment: A product manufacturer pointed out that under the proposal, new products would qualify as outlier services, and if we fail to allow separate payment at launch, there would be no ASP upon which to base an outlier payment. They recommend that we consider how to avoid jeopardizing beneficiary access by implementing an outlier payment based on wholesale acquisition cost (WAC) or another readily available price.

Response: We agree with the commenter that in the event we do not establish an ASP, WAC could be used. We consider WAC pricing to be a part of the pricing methodologies specified in section 1847A of the Act, and we would use the methodologies available to us under that authority in order to accurately determine a price for the calculation of outlier payments for new injectable and intravenous drugs that fit into one of the existing the functional categories.

ii. Transitional Drug Add-On Payment Adjustment

In the proposed rule (80 FR 37832), we explained that we anticipate that there may be new drugs that do not fall within the existing ESRD PPS functional categories and therefore, are not reflected in the ESRD PPS bundled payment. Where a new injectable or intravenous product is used to treat or manage a condition for which there is not a functional category, we proposed to pay for the new injectable or intravenous product using a transitional drug add-on payment adjustment under the authority of section 1881(b)(14)(D)(iv) of the Act. We proposed that the transitional drug add-on payment adjustment would be based on the ASP pricing methodology and would be paid until we have collected sufficient claims data for rate setting for the new injectable or intravenous product, but not for less than 2 years. We explained that a 2-year timeframe is necessary for adequate data collection, rate-setting and regulation development. We further explained that 2 years is necessary for rulemaking purposes because it is a year-long process that involves developing policies based on data, proposing those policies, allowing for public comment, finalizing the proposed rule, and allowing for a period of time before the rule becomes effective. We stated that the minimum 2-year period would also allow 1 year for payment of the adjustment to be paid before the beginning of a rulemaking cycle in which we could propose to add the drug to the bundled payment. For these reasons, we believed that 2 years was the minimum amount of time necessary to pay the adjustment and we proposed the regulation text for the transitional drug add-on payment adjustment at § 413.234(c).

In the proposed rule (80 FR 37832), we explained that paying a transitional drug add-on payment adjustment for new injectable and intravenous products would allow us to analyze price and utilization data for both the injectable and, if applicable, any oral or other forms of the drug in order to pay for the drugs under the ESRD PPS. We proposed that when a facility furnishes the new injectable drug they would report the drug to Medicare on the monthly facility bill and would append a CMS payment modifier that would instruct our claims processing systems to include a payment amount that equals the Part B drug payment amount, which is derived using the methodologies specified under section 1847A of the Act, which can include ASP + 6 percent pricing. We further explained that this payment approach is consistent with the policy we finalized in the CY 2013 ESRD PPS final rule (77 FR 67463), which states that we would use the ASP methodology, including any modifications finalized in the Physician Fee Schedule (PFS) final rules, to compute outlier MAP amounts, the drug add-on(formerly paid under the composite rate and no longer paid as part of the ESRD PPS), and any other policy that requires the use of payment amounts for drugs and biologicals that would be separately paid absent the ESRD PPS. We explained in the proposed rule that we would issue sub-regulatory billing and payment guidance along with the payment modifier in conjunction with our final rule guidance. Then, under the regulations at § 413.234(c), following payment of the transitional drug add-on payment adjustment, we would modify the ESRD PPS base rate, if appropriate, to account for the new injectable or intravenous product.

In the proposed rule (80 FR 37833), we noted that outlier payments would not be available for new injectable or intravenous products during the time in which these products are paid for using the new transitional drug add-on payment adjustment. We explained that while a new injectable drug or biological being paid using the transitional drug-add would otherwise be considered an outlier service because the drug or biological would have been considered separately billable prior to the implementation of the ESRD PPS, we do not believe that it would be appropriate to include the payment amount for the new drug or biological in the outlier calculation during this interim transition period. This is because during the interim period we would be making a payment for the specific drug in addition to the base rate, whereas outlier services have been incorporated into the base rate. For example, we have included the MAP amount for EPO in the base rate and it qualifies as an outlier. We noted that when the product is reflected in the base rate after payment of the transitional drug add-on payment adjustment, it would be considered eligible for outlier payments discussed in section II.B.2.c of this rule.

Comment: During the time in which a drug is paid for using the transitional drug add-on payment adjustment (2–3 years), a commenter stated that CMS would need to determine how dialysis facilities report new drug cost data. For example, CMS would need to determine whether it is appropriate to create a specific data element within the dialysis facility cost report to capture the cost of the eligible new drugs during the transition period and whether such data should be reported without any artificial cost limitations (otherwise imposed in the cost-reporting process) to ensure that, where appropriate, the true drug costs are reflected within the ESRD PPS base rate when the transition period ends. The commenter explained that based on the utilization data collected during the transition period, CMS would consider the prevalence of a new drug as a measure of whether it is essential for the delivery of dialysis (that is, an ESRD-related drug) or whether it should remain separately billable.

For example, if the utilization data show that a new drug is furnished to a *majority* of ESRD patients, then it would be considered ESRD-related, and the ESRD PPS base rate would be adjusted accordingly; conversely, if the data show that *less than a majority* of patients received the drug, then it would remain separately billable following the transition period. For drugs to be incorporated into the ESRD PPS, CMS should clarify how it will analyze the cost data and track cost following the transition period to ensure that the calculation used was accurate or whether revisions are required.

They also recommended that CMS work with stakeholders to develop a similar process so that transitional drug add-on payments are available until the ESRD bundle is appropriately recalibrated to accommodate the new class of products. They also recommended that we adopt a process

for determining when a drug is so costly that the ESRD PPS payment would be considered inadequate.

Response: We appreciate the suggestions for revisions to the ESRD cost report and the recommendation for capturing utilization data for new injectable and intravenous drugs used for the treatment of ESRD, and we will review the possibility of operationalizing these suggestions in the future. We recognize the importance of making new therapies available to ESRD patients and because of this, we will include new drugs that are determined to be renal dialysis services and fit into current functional groups. We plan to track utilization of all new renal dialysis service drugs, including those currently in the functional categories, those newly added to the functional categories, and those drugs that are candidates to be included in newly-created functional categories. We have heard from patients that they want to have access to new therapies and drugs. Through section 1881(b)(14)(A)(i) of the Act, the Congress requires the Secretary to implement the ESRD PPS, under which a single payment is made to a provider of services for renal dialysis services in lieu of any other payment. The renal dialysis services that are included in the ESRD PPS bundle are described in section 1881(b)(14)(B) of the Act and include other items and services furnished to individuals for the treatment of ESRD. The statutory definition of renal dialysis services is not limited to those services furnished to the majority of ESRD patients. Drugs that were separately billable were included in the ESRD PPS base rate, and the in CY 2011 final rule, those drugs were placed into categories. If renal dialysis service drugs fit into those functional categories, then they are included. This gives the patients access to those new drugs that fit into the functional categories. With regard to the recommendation that we adopt a process for determining when a drug is so costly that the ESRD PPS payment would be considered inadequate, we are concerned that establishing such a process for these drugs would lead to overpricing of drugs. We do, however, understand commenters' concerns and will consider addressing this issue in future rulemaking.

Comment: Some dialysis organizations are most concerned that a drug may be added to a functional category even if there is no competition for the new drugs in a given functional category. When there is no competition for a given drug, the commenters believe facilities are vulnerable to increased cost.

Response: We believe the commenter is referring to a new drug in a new functional category with no other drug in the category, leading to pricing vulnerability for the dialysis facilities. If the commenter is referring to what occurred with Epogen, with pricing being high due to a monopoly and lack of market competition, it may be that there will be only one drug in a new functional category for several years. All of the drugs in the current functional categories are populated by drugs that function well for the current ESRD population. The inclusion of the new drugs in these functional categories provides access for the beneficiaries to new renal dialysis services, including the drugs for the treatment of ESRD. When there is a new drug that does not fit into the current functional categories, a minimum of 2 years of utilization data is required before we will assess whether a functional category should be created through notice-and-comment rulemaking, as well as how to add the drug to the ESRD base rate. We believe it is in the best interest of the ESRD beneficiary to make these drugs available to them. We appreciate the commenter sharing their concern with us about competition within the functional categories.

Comment: A commenter expressed support for the use of the ASP pricing methodology for the transitional drug add-on payment adjustment for new drugs and biologicals that do not fall within the existing ESRD PPS functional categories. However, an organization representing small and medium dialysis facilities and an MDO are concerned that the proposed transitional add-on payment is calculated based on ASP, which has been shown not to be truly reflective of the actual cost of the drug. One organization pointed out that often there is a data lag between ASP and the actual cost of the drugs and as a result, the transitional add-on payment may not reflect the actual cost of the drug. A drug manufacturer recommended that the transitional drug add-on payment adjustment be set at ASP + 6 percent and the period of transition be set at 3 years.

Response: The ASP + 6 percent pricing methodology is a part of the pricing methodologies specified in section 1847A of the Act, which also include some wholesale acquisition cost (WAC) pricing during the first quarter of sales. We agree with the commenters that ASP + 6 percent pricing may not always be the most appropriate way to calculate the transitional drug add-on payment adjustment. Accordingly, we are revising the regulation text at 413.234(c)(1) to refer to the pricing methodologies under section 1847A of the Act, rather than ASP pricing methodology, because these methodologies include ASP, WAC, and Average Wholesale Pricing. Information regarding the pricing methodologies specified in 1847A of the Act can be found in Publication 100–04, Chapter 17—Drugs and Biologicals, section 20.1— MMA Drug Pricing—Average Sales Price.

After consideration of the public comments, we are finalizing the drug designation process and the corresponding regulation text at 42 CFR 413.234.

iii. Determination of When an Oral-Only Renal Dialysis Service Drug Is No Longer Oral-Only

Section 217(c)(1) of PAMA requires us to adopt a process for determining when oral-only drugs are no longer oral-only. In our CY 2011 ESRD PPS final rule (75 FR 49038 through 49039), we described oral-only drugs as those that have no injectable equivalent or other form of administration. In the proposed rule (80 FR 37833), we proposed to define the term oral-only drug as part of our drug designation process in our regulations at 42 CFR 413.234(a). For CY 2016, and in accordance with section 217(c)(1) of PAMA, we proposed that an oral-only drug would no longer be considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the FDA. We proposed to codify this process in our regulations at 42 CFR 413.234(d). In addition, we noted that the FDA posted lists of all drug dosages and forms of administration that are approved for use in the United States. For example, one of these lists can be viewed at *http://www.fda.gov/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/datastandardsmanualmonographs/ucm071666.*

A link for the drug and biologic approval and investigational new drug activity reports can be found at the following link: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/default.htm.*

In the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038), we noted that the only oral-only drugs and biologicals that we identified were phosphate binders and calcimimetics, which fall into the bone and mineral metabolism category. We defined these oral-only drugs as renal dialysis services in our regulations at § 413.171 (75 FR 49044), delayed the Medicare Part B payment for these oral-

only drugs until CY 2014 at § 413.174(f)(6), and continued to pay for them under Medicare Part D.

In the proposed rule (80 FR 37833), we explained that under our proposed drug designation process at § 413.234(b)(1), if injectable or intravenous forms of phosphate binders or calcimimetics are approved by the FDA, these drugs would be considered reflected in the ESRD PPS bundled payment because these drugs are included in an existing functional category so no additional payment would be available for inclusion of these drugs.

However, we recognized the uniqueness of these drugs and we proposed not to apply this process to injectable or intravenous forms of phosphate binders and calcimimetics when they are approved because payment for the oral forms of these drugs was delayed and dollars were never included in the base rate to account for these drugs. As we discussed above, we determined in CY 2011 that both classes of drugs (phosphate binders and calcimimetics) were furnished for the treatment of ESRD and are therefore renal dialysis services. In addition, in the proposed rule we explained that we had utilization data for both classes of drugs because the oral versions existed at that time. However, for reasons discussed in the CY 2011 ESRD PPS final rule (75 FR 49043 through 49044), we chose to delay their inclusion in the ESRD PPS bundled payment.

Therefore, in the proposed rule, we proposed that when a non-oral version of a phosphate binder or calcimimetic is approved by the FDA, we would include the oral and any non-oral version of the drug in the ESRD PPS bundled payment. Specifically, we proposed that we would develop a computation for the inclusion of the oral and non-oral forms of the phosphate binder or calcimimetic so that the drug could be appropriately reflected in the ESRD PPS base rate. We explained that we would not take this approach for any subsequent drugs that are approved by the FDA and fall within the bone and mineral metabolism functional category (or any other functional categories) because we did not delay payment for any other drugs or biologicals for which we had 2007 utilization data when the ESRD PPS was implemented in CY 2011 and, therefore, we believe the other functional categories appropriately reflect renal dialysis service drugs and biologicals.

Comment: A drug manufacturer expressed concern that the proposal did not address the computation or timing for adding the oral-only drugs into the bundled payment once an injectable or intravenous version is approved for use. The commenter assumes this process would be done through notice and comment rulemaking and urged CMS to specify this fact in the final rule. They pointed out the new drugs come on to the market throughout the year, which may or may not comport with the annual rulemaking cycle for the ESRD PPS.

Response: We intend to use notice-and-comment rulemaking to include the oral and non-oral forms of calcimimetics and phosphate binders in the ESRD PPS bundled payment after the payment of the transitional drug add-on payment adjustment. We will pay for calcimimetics and phosphate binders when those drugs are no longer oral-only drugs, that is, FDA approved and have an HCPCS code, using a transitional drug add-on payment adjustment calculated based on the payment methodologies in section 1847A of the Act. Once the injectable version is approved and has an HCPCS code we will issue a change request to provide notice that the injectable is available. Therefore, both the injectable and oral form will be paid under the ESRD PPS bundled payment using that adjustment. However, we note, any other new injectable or intravenous drug or biological will be assessed as to whether it fits into one of the functional categories. Injectable and intravenous drugs that fit into a functional category will not go through notice-and-comment rulemaking. Rather, they will be added to the functional categories, and thus the ESRD PPS, using a subregulatory process.

Comment: One of the drug manufacturers recommended that in the case of oral equivalents, that first in class drugs receive the full transitional drug add-on payment adjustment, with stepped down payments for new drugs in the same class entering the market during the transitional payment period for the first in class product.

One commenter stated that regardless of the method CMS uses to add these oral-only drugs to the ESRD PPS base rate, their inclusion should result in an increase in the base rate. They believe that PAMA's requirement to update payment rates using data from the most recent year available applies notwithstanding the budget neutrality adjustment that applied when the ESRD PPS was implemented in 2011.

Response: It is unclear whether the drug manufacturer is referring to the oral form of existing oral-only drugs, or oral equivalents of drugs for which there are other types of administration. Oral equivalents of drugs with another form of administration, as well as oral-only drugs other than calcimimetics and phosphate binders, will be subject to the drug designation process. However, for phosphate binders and calcimimetics—for which there is a functional category—but no money is in the base rate—we will utilize the transitional drug add-on payment adjustment to collect utilization data before adding this drug to the ESRD PPS base rate. Once money has been included in the base rate for an injectable or intravenous calcimimetic and phosphate binder in the bone and mineral metabolism functional category, any future injectable or intravenous drugs in this category will be added directly to the functional category and, thus, the bundled payment.

Comment: With regard to the definition of when an oral-only drug is no longer considered oral-only, two drug manufacturers expressed concern that the proposed regulatory text does not include an FDA reference as the standard for determining whether the FDA has approved another form of administration for a specific drug. They note that CMS provided a hyperlink in the proposed rule, but unfortunately, the link did not work. They recommended that we clarify in 42 CFR 413.234(d) whether we will specifically rely on the FDA publication ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the FDA Orange Book) for determining whether an oral drug has an injectable or non-oral form and is no longer in the oral-only category and should be included in the ESRD PPS payment. They point out that the FDA Orange Book identifies all drug products (including dosage forms, routes of administration, etc.) approved by the FDA. To help define terms used in these resources, they suggested we cite an up-to-date FDA Web site or resource that includes standards for identifying all drug dosage forms and routes of administration that are approved for use. If CMS is not using the FDA Orange Book, the commenters indicated that CMS should be specific in how it will determine whether a non-oral form of the oral-only drug exists.

A patient organization advocates that before oral-only drugs are incorporated into the bundle, certain measures must be in place to ensure that drugs are appropriate for patients and that costs for the drugs are accurately calculated and paid for. Two pharmaceutical manufacturers recommended that, to avoid confusion, CMS should clarify in the regulation text that CMS will exclude a drug that meets the definition

of an oral-only drug and has no injectable or other form of administration.

Response: We thank the commenters for making us aware of the non-working link and have corrected that link in this final rule. The publication titled ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). The ''Orange Book Search'' was added to the FDA Web site October 31, 1997. We will utilize the Orange Book to assist us in determining whether an injectable or other form of administration of an oral-only drug has been approved by the FDA. When an oral-only drug already determined to be a renal dialysis service is formulated for injectable or intravenous use it will no longer be considered an oral-only drug. The new injectable or intravenous form of the oral-only drug will be assessed as to whether it fits into one of the functional groups. If it does not fit into the current functional groups, a new functional group will be proposed through notice-and-comment rulemaking. Other than oral drugs included in the ESRD PPS bundle that were composite rate drugs, if there is no injectable or intravenous form of an oral-only drug used for the treatment of ESRD, then it is not considered a part of the ESRD PPS bundle, and is paid for separately. Regarding the costs for the drugs being accurately calculated and paid for, we appreciate the commenter's concerns and anticipate addressing the possibility of these unique situations in future rulemaking.

Regarding the recommendation that CMS should clarify in the regulation text that CMS will exclude a drug that meets the definition of an oral-only drug and has no injectable or other form of administration, we note that the Congress excluded oral-only drugs from the ESRD PPS payment bundle. Payments for oral-only ESRD drugs are not included under the ESRD PPS until 2024 as required by section 632(b)(1) of ATRA, as amended by section 217(a) of PAMA. Section 204 of ABLE further amended section 632(b)(1) of ATRA to provide that payment for oral-only ESRD drugs cannot be made under the ESRD PPS prior to January 1, 2025.

Comment: A national dialysis organization, LDOs, and a professional association stated that when an injectable or intravenous calcimimetic has been approved by the FDA and becomes available, many factors will need to be assessed, including clinical guidelines and indications, which may vary between injectable or intravenous and oral products; utilization and costs per treatment; and range of dosing. One LDO believes that there is insufficient information available regarding the future injectable or intravenous and oral products upon which to base sound payment policy. They pointed out that the oral calcimimetics are used by one-third of their patients. That sizeable population combined with the significant cost of the drug makes it unlikely that the current outlier policy would be sufficient to address utilization differences in patient population among facilities. They requested that CMS allow the injectable or intravenous equivalent of oral Sensipar to remain outside of the bundle for a transition period. Data collected from this period can guide the formation of reimbursement policy to ensure that beneficiaries have proper access to the therapy, that is, injectable, intravenous, or oral, which is best for them according to the severity of their secondary hyperparathyroidism.

A national dialysis organization recommends that at the end of a 2-year transition period, CMS would value the cost of the injectable or intravenous calcimimetic under Part B, including beneficiary costs, and add that amount to the base rate, if utilization warrants the costs to be spread across all patients. Relying upon the Part D spending data alone would assume that oral drug spending is the same as it would be for an injectable or intravenous, but very little is known about how the drug will be used in the ESRD population. Some commenters are requesting a 2-year delay in incorporating payment for calcimimetics under the ESRD PPS. In addition, they expressed concern that spending for calcimimetics under Part D does not represent all the utilization and dollars because some ESRD patients have no drug plan or are subject to the Part D ''donut hole'' due to cost. The organization expects that migration of payment from Part D to Part B will increase utilization among this group. The organization pointed out that including calcimimetics under the ESRD PPS will increase Part B expenditures and that the ESRD PPS cannot absorb the cost of calcimimetics without a substantial increase to the base rate. Another large stakeholder supports a transitional payment for injectable or intravenous versions of phosphate binders and calcimimetics because the bundled payment could be improperly inflated by a higher costing injectable or intravenous version that is only benefitting a subset of patients, but all patients would be subjected to a higher coinsurance. Conversely, there could be superior benefit of the injectable or intravenous version that renders the utilization of the oral versions lower.

A drug manufacturer asked how CMS would determine the cost associated with a new drug if there is no utilization data, what sources of data CMS would use to measure utilization of an oral drug by beneficiaries not enrolled in Part D and whether payment rates could be adjusted mid-year to provide timely payment for new drugs upon approval or launch. They expressed concern that not having utilization for the 30 percent of beneficiaries without Part D coverage will likely result in an inappropriate payment amount. The manufacturer also expressed concern that payments for new injectable or intravenous versions of oral-only drugs will also be inaccurate if the amount is based solely on Part D data. The manufacturer recommended that CMS conduct analyses to determine the adherence rate for the oral-only products using Part D claims to measure the medication possession ratio (MPR) and, assuming 2100 percent adherence under Part B, estimate the gap that needs to be accounted for in the payment computation. MPR has been shown to be a useful metric in measuring patient adherence.

A professional association agrees with paying ASP+6percent for injectable or intravenous treatments for bone and mineral disorders until the utilization of the new product is sufficiently mature to be subsumed into the PPS with accurate cost and use data.

Another commenter was also concerned about the timing of the roll-out of the injectable or intravenous phosphate binders and calcimimetics with the annual rulemaking cycle for the ESRD PPS. They are concerned about the ability for dialysis facilities to adopt a new non-oral calcimimetic or phosphate binder if there is no opportunity for payment until the next calendar year.

Response: We thank the commenters for their input regarding the process for including calcimimetics and phosphate binders in the ESRD PPS bundled payment. We agree with the industry that injectable or intravenous phosphate binders and calcimimetics that come on the market in the future could have different clinical indications, utilization patterns, and costs than the oral-only versions and we believe it is appropriate to pay for these drugs using the transitional drug add-on payment adjustment for a minimum of 2 years.

Once the injectable or intravenous phosphate binder or calcimimetic are FDA approved and have a HCPCS code, we will issue a change request (as stated above) to pay for all forms of the phosphate binder or calcimimetic using a transitional drug add-on payment based on the payment methodologies under section 1847A of the Act, which could include ASP+6 percent, for a period of at least 2 years. This will allow us to collect data reflecting current utilization of both the oral and injectable or intravenous forms of the drugs, as well as payment patterns and beneficiary co-pays before we add these drugs to the ESRD PPS bundle. During this period we will not pay outlier payments for these drugs. At the end of the 2 or more years, the methodology for including the phosphate binders and calcimimetics into the ESRD PPS bundled payment will be adopted through notice-and-comment rulemaking.

Regarding the drug manufacturer's recommendation that CMS conduct analyses to determine the adherence rate for the oral-only products using Part D claims to measure the medication possession ratio (MPR) because MPR has been shown to be a useful metric in measuring patient adherence, we will rely on utilization data from the dialysis facilities, which are required to report all separately billable drugs.

We appreciate the support of the professional association for the use of the ASP pricing methodology for the transitional drug add-on payment adjustment and the minimum 2-year timeframe for payment of the adjustment, which we also agree is necessary to collect utilization data for these drugs.

After consideration of public comments, we are finalizing the definition of oral-only drug at 413.234(a), which provides that an oral-only drug is a drug or biological with no injectable equivalent or other form of administration other than an oral form. We are also finalizing our process at 42 CFR 413.234(d) for determining that an oral only drug is no longer considered oral-only when a non-oral version of the oral-only drug is approved by the FDA. We will include the oral and any non-oral version of the drug in the ESRD PPS bundled payment when it is no longer considered an oral-only drug under this regulation. For at least 2 years we will pay for the existing oral-only drugs—phosphate binders and calcimimetics—using the transitional drug add-on payment adjustment, which will be calculated based on the payment methodologies under section 1847A of the Act. We will add the oral and non-oral forms of the phosphate binders and calcimimetics to the ESRD PPS bundled payment through notice-and-comment rulemaking. For future oral-only drugs for which a non-oral form of administration comes on the market, we will apply our drug designation process as we would for all other new drugs.

4. Delay of Payment for Oral-Only Renal Dialysis Services

As we discussed in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186) and again in the CY 2015 ESRD PPS final rule (79 FR 66147 through 66148), section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services, and subclause (iii) of such section states that these services include other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological.

We interpreted this provision as including not only injectable drugs and biologicals used for the treatment of ESRD (other than ESAs and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act), but also all oral drugs and biologicals used for the treatment of ESRD and furnished under title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biologicals used for the treatment of ESRD do not fall within clause (iii) of section 1881(b)(14)(B), such drugs or biologicals would fall under clause (iv) of such section, and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B).

We finalized and promulgated the payment policies for oral-only renal dialysis service drugs or biologicals in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053), where we defined renal dialysis services at 42 CFR 413.171 as including other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately prior to January 1, 2011 under Title XVIII of the Act, including drugs and biologicals with only an oral form. Although we included oral-only renal dialysis service drugs and biologicals in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for these drugs under the PPS until January 1, 2014. We stated that there were certain advantages to delaying the implementation of payment for oral-only drugs and biologicals, including allowing ESRD facilities additional time to make operational changes and logistical arrangements in order to furnish oral-only renal dialysis service drugs and biologicals to their patients. Accordingly, we codified the delay in payment for oral-only renal dialysis service drugs and biologicals at 42 CFR 413.174(f)(6), and provided that payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form is incorporated into the PPS payment rates effective January 1, 2014.

On January 3, 2013, ATRA was enacted. Section 632(b) of ATRA precluded the Secretary from implementing the policy under 42 CFR 413.176(f)(6) relating to oral-only renal dialysis service drugs and biologicals prior to January 1, 2016. Accordingly, in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), we delayed payment for oral-only renal dialysis service drugs and biologicals under the ESRD PPS until January 1, 2016. We implemented this delay by revising the effective date at § 413.174(f)(6) for providing payment for oral-only renal dialysis service drugs under the ESRD PPS from January 1, 2014 to January 1, 2016. In addition, we changed the date when oral-only renal dialysis service drugs and biologicals would be eligible for outlier services under the outlier policy described in § 413.237(a)(1)(iv) from January 1, 2014 to January 1, 2016.

On April 1, 2014, PAMA was enacted. Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA, which now precludes the Secretary from implementing the policy under 42 CFR 413.174(f)(6) relating to oral-only renal dialysis service drugs and biologicals prior to January 1, 2024. We implemented this delay in the CY 2015 ESRD PPS final rule (79 FR 66262) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biologicals under the ESRD PPS at § 413.174(f)(6) from January 1, 2016 to January 1, 2024. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2016 to January 1, 2024.

In the CY 2016 ESRD PPS proposed rule (80 FR 37834) we stated that on December 19, 2014, section 204 of ABLE was enacted, which delays the inclusion of renal dialysis service oral-only drugs and biologicals under the ESRD PPS until 2025. It amended section 632(b)(1)

of ATRA, as amended by section 217(a)(1) of PAMA by striking ''2024'' and inserting ''2025.'' We explained that as we did in the CY 2014 ESRD PPS final rule (78 FR 72186) and the CY 2015 ESRD PPS final rule (79 FR 66148) referenced above, we proposed to implement this delay by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biologicals under the ESRD PPS at 42 CFR 413.174(f)(6) from January 1, 2024 to January 1, 2025. In addition, we proposed to change the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2024 to January 1, 2025.We stated that we continue to believe that oral-only renal dialysis service drugs and biologicals are an essential part of the ESRD PPS bundle and should be paid for under the ESRD PPS.

We did not receive any comments on implementing the delay by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biologicals under the ESRD PPS at 42 CFR 413.174(f)(6) from January 1, 2024 to January 1, 2025. In addition we did not receive comments on the change to the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2024 to January 1, 2025. Therefore, we are finalizing the language at 42 CFR 413.174(f)(6) and § 413.237(a)(1)(iv) as proposed.

5. Reporting Medical Director Fees on ESRD Facility Cost Reports

In the 1980s, following audits by the Office of the Inspector General and the Medicare administrative contractors (MACs) that revealed instances in which independent facilities compensated their medical directors and administrators excessively, CMS set limits for reasonable compensation when reporting medical director fees on ESRD facility cost reports. End-Stage Renal Disease Program; Prospective Reimbursement for Dialysis Services and Approval of Special Purpose Renal Dialysis Facilities, 48 FR 21254, 21261 through 21262 (May 11, 1983); End-Stage Renal Disease Program: Composite Rates and Methodology for Determining the Rates, 51 FR 29404, 29407 (Aug. 15, 1986). In Transmittal 12, issued in July 1989, of the Provider Reimbursement Manual Part I, Chapter 27, titled, ''Reimbursement for ESRD and Transplant Services,'' CMS adopted a policy for reporting allowable compensation for physician owners and medical directors of ESRD facilities and set a limit at the Reasonable Compensation Equivalent (RCE) limit of the specialty of internal medicine for a metropolitan area of greater than one million people.

In the Provider Reimbursement Manual Part I, Chapter 27—Outpatient Maintenance Dialysis Services, 2723—Responsibility of Intermediaries, we explain that the intermediary reviews facility cost reports to ensure that the compensation paid to medical directors does not exceed the RCE limit. The RCE limit for a board-certified physician of internal medicine has been updated over the interim years. The most recent update to the RCE limit was finalized in the FY 2015 IPPS final rule published on August 22, 2014 (79 FR 50157 through 50162). In that rule, CMS finalized an RCE limit of $197,500 per year beginning in CY 2015 for a board-certified physician of internal medicine.

The requirements for medical directors of ESRD facilities are discussed in the Conditions for Coverage for ESRD facilities, which were updated in 2008 to reflect advances in dialysis technology and standard care practices since the requirements were last revised in their entirety in 1976. Conditions for Coverage for ESRD Facilities, 73 FR 20470 (April 15, 2008). With the update to the Conditions for Coverage, all Medicare-certified ESRD facilities are required to have a medical director who is responsible for the delivery of patient care and outcomes in the facility as codified in 42 CFR part 494, titled Conditions for Coverage for End-Stage Renal Disease Facilities. We discuss the qualifications of an ESRD facility medical director in 42 CFR 494.140(a), titled Standard: Medical director, where we require that a medical director must be a board-certified physician in internal medicine or pediatrics by a professional board and have completed a board-approved training program in nephrology with at least 12 months of experience providing care to patients receiving dialysis, but if such a physician is not available, another physician may direct the facility, subject to the approval of the Secretary.

In the CY 2016 ESRD PPS proposed rule (80 FR 37834), we explained that the RCE limit of $197,500 per year for a board-certified physician of internal medicine may be less than the expense a facility incurs if they employ a board-certified nephrologist as their medical director.In that rule, we stated that we could appreciate that the reasonable compensation limits are generally used when determining payment for providers that are reimbursed on a reasonable cost basis; they typically are not used in prospective payment systems, like the ESRD PPS, that update payment rates using market basket methodologies. We further stated that we believe the application of the RCE limit is no longer relevant now that 100 percent of ESRD facilities are paid under the ESRD PPS beginning in CY 2014.

Therefore, we proposed that beginning in CY 2016 we would eliminate the RCE limit for reporting an ESRD facility's medical director fees on ESRD facility cost reports. We noted that the elimination of the RCE limit does not supersede or alter in any way the reporting guidance furnished in the Provider Reimbursement Manual, Part 2, Chapter 42, sections 4210, 4210.1 and 4210.2. In addition, we stated that we will continue to apply the ESRD facility-specific policy under which the time spent by a physician in an ESRD facility on administrative duties is limited to 25 percent per facility unless documentation is furnished supporting the claim. In addition, if an individual provides services to more than one dialysis facility, the individual's time must be prorated among the different facilities and may not exceed 100 percent.

The comments and our responses are set forth below.

Comment: Several national dialysis organizations expressed support for the CMS proposal to eliminate limits on medical director fees reported on cost reports. The commenters requested that we apply this policy change to the 2015 cost reports.

Response: We thank the commenters for their support of the proposal to eliminate the limit for medical director fees on the ESRD facility cost report. This policy change is effective January 1, 2016 for CY 2016. Since the policy is effective for CY 2016, we are not able to apply this policy to cost reports before the effective date and therefore it will not be applicable to the CY 2015 cost reports.

Comment: MedPAC urged CMS to maintain a limit for reporting an ESRD facility's medical director fees on ESRD facility cost reports. They believe the current RCE limit on the medical director compensation creates pressure on facilities to constrain their compensation costs and make better use of beneficiaries' and taxpayers' resources. In addition, eliminating the RCE limit may decrease some facilities' negotiating leverage with prospective medical directors, which in turn, will lead to increased compensation costs. The commenter explained that as providers' costs increase, all other things being equal, the resulting

Medicare margin will decrease. MedPAC suggested that, as an alternative to the current RCE limit or no compensation limit, that we adopt a limit used by other Executive branch agencies such as the Title 38 Physician and Dentist Pay under which pay table 2 includes nephrology as a covered clinical specialty and the pay range for the most senior management level is $140,000 to $250,000.

Response: We do not believe that perpetuating a limit for the medical director fee is appropriate for the reasons that we discuss above, including that ESRD facilities are no longer reimbursed on a cost basis. This policy change will not affect the ESRD PPS annual update or increase Medicare spending. In addition, MACs perform a general reasonableness evaluation of a person's compensation by comparing it with the compensation paid to other individuals in similar circumstance. We believe that the elimination of the limit will more accurately represent facility costs on the cost report that is used for margin analysis or refinements to the payment system.

Based on the comments that we received, we are finalizing that beginning in CY 2016 we are eliminating the RCE limit for reporting an ESRD facility's medical director fees on ESRD facility cost reports.

C. Clarifications Regarding the ESRD PPS

1. Laboratory Renal Dialysis Services

Section 1881(b)(14)(B)(iv) of the Act requires diagnostic laboratory tests not included under the composite payment rate (that is, laboratory services separately paid prior to January 1, 2011) to be included as part of the ESRD PPS payment bundle. In the CY 2011 ESRD PPS final rule (75 FR 49053), we defined renal dialysis services at 42 CFR 413.171 to include items and services included in the composite payment rate for renal dialysis services as of December 31, 2010 and diagnostic laboratory tests and other items and services not included in the composite rate that are furnished to individuals for the treatment of ESRD. The composite payment rate covered routine items and services furnished to ESRD beneficiaries for outpatient maintenance dialysis, including some laboratory tests. We finalized a policy to include in the definition of laboratory tests under 42 CFR 413.171(4) those laboratory tests that were separately billed by ESRD facilities as of December 31, 2010 and laboratory tests ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD patients that were separately billed by independent laboratories (75 FR 49055). We determined the average Medicare Allowable Payment (MAP) amount was $8.40, as listed on Table 19 titled, ''Average Medicare Allowable Payments for composite rate and separately billable services, 2007, with adjustment for price inflation to 2009'' (75 FR 49075). This amount included the laboratory tests that were already included under the composite rate, as well as laboratory tests billed separately by ESRD facilities (that is, all laboratory services paid on the 72X claim furnished in CY 2007) and laboratory tests that were ordered by Monthly Capitation Payment (MCP) practitioners that were separately billed by independent labs in CY 2007.

Through the comments we received on the CY 2011 ESRD PPS proposed rule, we learned that holding the ESRD facilities responsible for any laboratory test that is furnished in the ESRD facility or ordered by an MCP could have unintended consequences to patients (75 FR 49054). In particular, commenters noted that in many instances the MCP physician is the ESRD patient's primary care physician and often orders laboratory tests that are unrelated to the patient's ESRD. These commenters raised concerns that requiring ESRD facilities to pay for these tests would result in large numbers of tests that are unrelated to ESRD being included in the ESRD bundle. We agreed with commenters that it would be in the best interest of the beneficiaries for an ESRD facility to draw blood for laboratory tests that are not for the treatment of ESRD during the dialysis session.

Commenters also requested that we produce a list of the ESRD-related laboratory tests that are included in the ESRD PPS bundle (75 FR 49054). We received several laboratory service lists from the commenters that they considered to be generally furnished for the treatment of ESRD. While there was agreement for many of the laboratory services, the lists were inconsistent and lacked stakeholder consensus. When Medicare provides a payment for a benefit that is based on a bundle of items and services, CMS establishes claims processing edits that prevent payment in other settings for items and services that are identified as being accounted for in the bundled payment. Therefore, we needed to develop a list of ESRD-related laboratory tests to implement claims processing edits that prevent payment in other settings for items and services that are identified as renal dialysis services to ensure that payment is not made to independent laboratories for ESRD-related laboratory tests. Under the ESRD PPS we call these edits consolidated billing (CB) requirements.

We performed a clinical review of the lists provided by the industry and the laboratory tests reported in the claims data to determine which laboratory tests are routinely furnished to ESRD beneficiaries for the treatment of ESRD. Our clinical review resulted in Table F in the Addendum of the CY 2011 ESRD PPS final rule as the list of laboratory tests that are subject to the ESRD PPS CB requirements (75 FR 49213). We acknowledged in that rule that the list of laboratory tests displayed in Table F is not an all-inclusive list and we recognized that there are other laboratory tests that may be furnished for the treatment of ESRD (75 FR 49169). We stated in the Medicare Benefit Policy Manual, Pub. 100–02, Chapter 11, section 20.2, that the determination of whether a laboratory test is ESRD-related is a clinical decision for the ESRD patient's ordering practitioner. If a laboratory test is ordered for the treatment of ESRD, then the laboratory test is not paid separately.

Due to the commenters' concerns that ESRD beneficiaries should be able to have blood drawn for non-ESRD-related laboratory tests in the ESRD facility, we created a methodology for allowing ESRD facilities to receive separate payment when a laboratory service is furnished for reasons other than for the treatment of ESRD (75 FR 49054). We created CB requirements using a modifier to allow independent laboratories, hospital-based laboratories, or ESRD facilities (with the appropriate clinical laboratory certification in accordance with the Clinical Laboratory Improvement Amendments), to receive separate payment. This modifier, which is called the AY modifier, serves as an attestation that the item or service is medically necessary for the patient but is not being used for the treatment of ESRD.

In the CY 2016 ESRD PPS proposed rule (80 FR 37835), we explained that following publication of the CY 2011 ESRD PPS final rule, we had received numerous inquiries regarding Table F (75 FR 49213). Stakeholders have communicated to us that having a list of laboratory services that is not all-inclusive is confusing because there is no definitive guidance on which laboratory tests are included in, and excluded from, the ESRD PPS. They further stated that leaving the determination of when a laboratory test is ordered for the treatment of ESRD to the practitioner creates inconsistent billing practices and potential overuse

of the AY modifier. Stakeholders stated that practitioners can have different positions on when a laboratory test is being ordered for the treatment of ESRD. For example, some practitioners may believe that laboratory tests ordered commonly for diabetes could be considered as for the treatment of ESRD because in certain situations a patient's ESRD is a macrovascular complication of the diabetes. Commenters believe these varying perspectives among practitioners can translate into inconsistent billing practices.

In the proposed rule (80 FR 37835 through 37836), we also explained that stakeholders have expressed concern about potential overuse of the AY modifier because they are aware that CMS monitors the claims data for trends and behaviors. The industry's position is that if there is a laboratory service that is subject to the CB requirements, it is because CMS has determined that test to be routinely furnished for the treatment of ESRD and if certain tests are frequently reported with the AY modifier, then those laboratories or ESRD facilities could appear to be inappropriately billing Medicare.

In the proposed rule (80 FR 37836) we explained that while we recognize stakeholders' concerns, for CY 2016, we did not make a proposal to change the laboratory services policy and reiterated that any laboratory test furnished to an ESRD beneficiary for the treatment of ESRD is considered to be a renal dialysis service and is not payable outside of the ESRD PPS. We explained that we continue to believe that it is necessary to use a list of laboratory services that are routinely furnished for the treatment of ESRD for enforcing the CB requirements. In addition, we continue to believe it is convenient for ESRD beneficiaries to have their blood drawn at the time of dialysis for laboratory testing for reasons other than for the treatment of ESRD.

In the proposed rule (80 FR 37836) we stated that we have included appropriate payments into the base rate to account for any laboratory test that a practitioner determines to be used for the treatment of ESRD. We explained that it is important that medical necessity be the reason for how items and services are reported to Medicare. When services are reported appropriately, payments are made appropriately out of the Trust Fund and ESRD beneficiaries are not unfairly inconvenienced by constraints placed upon them because a certain laboratory test is or is not included in the ESRD PPS. Therefore, in order to maintain practitioner flexibility for ordering tests believed to be medically necessary for the treatment of ESRD, and have those tests included and paid under the ESRD PPS, we did not make a proposal to adopt a specific list of laboratory services that are always considered furnished for the treatment of ESRD.

We solicited comment on the current list of laboratory services that is used for the ESRD PPS CB requirements to determine if there is consensus among stakeholders regarding whether the list includes those laboratory tests that are routinely furnished for the treatment of ESRD. Table 9is the list of laboratory tests that is used for the CB requirements. We explained in the proposed rule (80 FR 37836) that we agree with the stakeholders that there can be different interpretations among practitioners as to what is considered to be furnished for the treatment of ESRD and that there can be some views that are more conservative than others. Furthermore it is the patient's ordering practitioner who makes the clinical determination of whether a laboratory test is for the treatment of ESRD.

We did not receive comments from stakeholders indicating if the list of laboratory services used for CB requirements are or are not routinely furnished for the treatment of ESRD.

In the proposed rule (80 FR 37836), we stated that in the context of the clarification, we proposed to remove the lipid panel from the CB list. As we stated in the CY 2013 ESRD PPS final rule (77 FR 67470), it was our understanding that the lipid panel was routinely used for the treatment of ESRD. We explained that because some forms of dialysis, particularly peritoneal dialysis, are associated with increased cholesterol and triglyceride levels, a lipid profile laboratory test to assess these levels would be considered furnished for the treatment of ESRD. In the CY 2016 proposed rule (80 FR 37836) we indicated that since the CY 2013 final rule was published we have learned from stakeholders that the lipid panel is mostly used to monitor cardiac conditions and is not routinely furnished for the treatment of ESRD.

We explained that we believed that the proposal to remove the lipid panel was consistent with the clarification provided in that rule that laboratory services included in Table 9and subject to ESRD consolidated billing are those that are routinely furnished for the treatment of ESRD but that may occasionally be used to treat non-ESRD-related conditions. In contrast, the lipid profile laboratory test is not routinely used for the treatment of ESRD. We solicited comments on this proposal and received several comments as set forth below.

Comment: Many stakeholders (an LDO, two national dialysis organizations, an organization representing small and medium dialysis facilities, and a nonprofit dialysis organization, and two professional associations)expressed support for the proposed elimination of the lipid panel from the consolidated billing list.

Response: We appreciate the commenters support. We are finalizing the removal of the lipid panel from the ESRD PPS consolidated billing list and we will issue subregulatory guidance to that effect. However, we note that even though lipid panels are being removed from the ESRD PPS consolidated billing list, if an ESRD patient's ordering practitioner orders a lipid panel for the treatment of ESRD then it should not be billed separately.

TABLE 9—LABORATORY SERVICES SUBJECT TO ESRD CONSOLIDATED BILLING

Short description	CPT/HCPCS
Basic Metabolic Panel (Calcium, ionized)	80047
Basic Metabolic Panel (Calcium, total)	80048
Electrolyte Panel	80051
Comprehensive Metabolic Panel	80053
Lipid Panel [1]	80061
Renal Function Panel	80069
Hepatic Function Panel	80076
Assay of serum albumin	82040
Assay of aluminum	82108
Vitamin d, 25 hydroxy	82306
Assay of calcium	82310
Assay of calcium, Ionized	82330
Assay, blood carbon dioxide	82374
Assay of carnitine	82379
Assay of blood chloride	82435
Assay of creatinine	82565
Assay of urine creatinine	82570
Creatinine clearance test	82575
Vitamin B–12	82607
Vit d 1, 25-dihydroxy	82652
Assay of erythropoietin	82668
Assay of ferritin	82728
Blood folic acid serum	82746
Assay of iron	83540
Iron binding test	83550
Assay of magnesium	83735
Assay of parathormone	83970
Assay alkaline phosphatase	84075
Assay of phosphorus	84100
Assay of serum potassium	84132
Assay of prealbumin	84134
Assay of protein, serum	84155
Assay of protein by other source	84157
Assay of serum sodium	84295
Assay of transferrin	84466
Assay of urea nitrogen	84520
Assay of urine/urea-n	84540
Urea-N clearance test	84545
Hematocrit	85014
Hemoglobin	85018

TABLE 9—LABORATORY SERVICES SUBJECT TO ESRD CONSOLIDATED BILLING—Continued

Short description	CPT/HCPCS
Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count) and automated differential WBC count	85025
Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count)	85027
Automated rbc count	85041
Manual reticulocyte count	85044
Automated reticulocyte count	85045
Reticyte/hgb concentrate	85046
Automated leukocyte count	85048
Hep b core antibody, total	86704
Hep b core antibody, igm	86705
Hep b surface antibody	86706
Blood culture for bacteria	87040
Culture, bacteria, other	87070
Culture bacteri aerobic othr	87071
Culture bacteria anaerobic	87073
Cultr bacteria, except blood	87075
Culture anaerobe ident, each	87076
Culture aerobic identify	87077
Culture screen only	87081
Hepatitis b surface ag, eia	87340
CBC/diff wbc w/o platelet	G0306
CBC without platelet	G0307

[1] Effective January 1, 2016, this laboratory service is no longer subject to the ESRD PPS consolidated billing requirements.

In the proposed rule (80 FR 37836), we explained that although we did not propose to change our policy related to payment for ESRD-related laboratory services under the ESRD PPS, we did clarify that to the extent a laboratory test is performed to monitor the levels or effects of any of the drugs that we have specifically excluded from the ESRD PPS, these tests would be separately billable. In the CY 2011 ESRD PPS final rule, we discuss when certain drugs and biologicals would not be considered for the treatment of ESRD. Specifically, Table 10, which appeared as Table 3—ESRD Drug Category Excluded from the Final ESRD PPS Base Rate in the CY 2011 ESRD PPS final rule (75 FR 49049) lists the drug categories that were excluded from the ESRD PPS and the rationale for their exclusion. In the proposed rule, we clarified that laboratory services furnished to monitor the medication levels or effects of drugs and biologicals that fall in those categories would not be considered to be furnished for the treatment of ESRD. We solicited comment on this clarification and a summary of those comments are set forth below.

Comment: Several organizations expressed support for the clarification of linking coverage of laboratory testing under the ESRD PPS to the drugs and biologicals considered to be renal dialysis services. They indicated that they support the clarifications that a laboratory test that is performed to monitor the levels or effects of any of the drugs that CMS has specifically excluded from the ESRD PPS will be separately billable and not be considered to be furnished for the treatment of ESRD.

Response: We appreciate the commenters support and will update our subregulatory guidance with this clarification.

Comment: One health plan requested that we also remove Vitamin D/Hydroxy lab service (CPT 82306) as this lab is not routinely or consistently provided to ESRD patients and not necessary for the treatment of ESRD. Stakeholders stated that considering any laboratory test furnished to an ESRD beneficiary for the treatment of ESRD to be a renal dialysis service and therefore not payable outside of the ESRD PPS is imprecise and harms all parties involved—including dialysis facilities, independent laboratories, and patients—by guaranteeing widespread inconsistent billing practices and unpredictable medical review outcomes, and by ignoring the fundamental principles of consolidated billing and the PPS methodology, which depend on predictability to enable efficient cost management. Instead they recommend that CMS adopt an objective standard, such as clearly stating that laboratory tests included in the consolidated billing list constitutes an all-inclusive list of laboratory tests included in the ESRD PPS.

Response: We plan to reassess the laboratory services policies under the ESRD PPS, including whether to establish an all-inclusive list of laboratory tests, in light of the clarification of our policy that links laboratory tests under the ESRD PPS with renal dialysis service drugs. With regard to the specific suggestion that we remove Vitamin D/Hydroxy laboratory service, we will address this suggestion in future guidance once we assess the extent to which the laboratory test is used and whether it is related to renal dialysis service drugs.

TABLE 10—ESRD DRUG CATEGORIES EXCLUDED FROM THE FINAL ESRD PPS BASE RATE

Drug category	Rationale for exclusion
Anticoagulant	Drugs labeled for non-renal dialysis conditions and not for vascular access.
Antidiuretic	Used to prevent fluid loss.
Antiepileptic	Used to prevent seizures.
Anti-inflammatory	May be used to treat kidney disease (glomerulonephritis) and other inflammatory conditions.
Antipsychotic	Used to treat psychosis.
Antiviral	Used to treat viral conditions such as shingles.
Cancer management	Includes oral, parenteral and infusions. Cancer drugs are covered under a separate benefit category.
Cardiac management	Drugs that manage blood pressure and cardiac conditions.
Cartilage	Used to replace synovial fluid in a joint space.
Coagulants	Drugs that cause blood to clot after anti-coagulant overdose or factor VII deficiency.
Cytoprotective agents	Used after chemotherapy treatment.
Endocrine/metabolic management	Used for endocrine/metabolic disorders such as thyroid or endocrine deficiency, hypoglycemia, and hyperglycemia.
Erectile dysfunction management	Androgens were used prior to the development of ESAs for anemia management and currently are not recommended practice. Also used for hypogonadism and erectile dysfunction.
Gastrointestinal management	Used to treat gastrointestinal conditions such as ulcers and gallbladder disease.
Immune system management	Anti-rejection drugs covered under a separate benefit category.
Migraine management	Used to treat migraine headaches and symptoms.
Musculoskeletal management	Used to treat muscular disorders such as prevent muscle spasms, relax muscles, improve muscle tone as in myasthenia gravis, relax muscles for intubation and induce uterine contractions.

TABLE 10—ESRD DRUG CATEGORIES EXCLUDED FROM THE FINAL ESRD PPS BASE RATE—Continued

Drug category	Rationale for exclusion
Pharmacy handling for oral anti-cancer, anti-emetics and immunosuppressant drugs.	Not a function performed by an ESRD facility.
Pulmonary system management	Used for respiratory/lung conditions such as opening airways and newborn apnea.
Radiopharmaceutical procedures	Includes contrasts and procedure preparation.
Unclassified drugs	Should only be used for drugs that do not have a HCPCS code and therefore cannot be identified.
Vaccines	Covered under a separate benefit category.

2. Renal Dialysis Service Drugs and Biologicals

a. 2014 Part D Call Letter Follow-Up

In the proposed rule (80 FR 37837), we explained that last year we received public comments that expressed concern that the 2014 Part D Call Letter provision for prior authorization for drug categories that may be used for ESRD as well as other conditions resulted in Part D plan sponsors inappropriately refusing to cover oral drugs that are not renal dialysis services. Specifically, they noted that beneficiaries had difficulties obtaining necessary medications such as oral antibiotics prescribed for pneumonia and that the 2014 Part D Call Letter provision led to confusion for Part D plan sponsors and delays in beneficiaries obtaining essential medications at the pharmacy.

In response to the comments, we explained that the guidance in the 2014 Part D Call Letter was issued in response to increases in billing under Part D for drugs that may be prescribed for renal dialysis services but may also be prescribed for other conditions. The guidance strongly encouraged Part D sponsors to place beneficiary-level prior authorization edits on all drugs in the seven categories identified in the CY 2011 ESRD PPS final rule as drugs that may be used for dialysis and non-dialysis purposes (75 FR 49051). These include: antiemetics, anti-infectives, anti-pruritics, anxiolytics, drugs used for excess fluid management, drugs used for fluid and electrolyte management including volume expanders, and drugs used for pain management (analgesics). We indicated in the CY 2015 ESRD PPS final rule (79 FR 66151) that we were considering various alternatives for dealing with this issue, as it has always been our intention to eliminate or minimize disruptions or delays in ESRD beneficiaries receiving essential medications and that we planned to issue further guidance to address the issue.

In the Health Plan Management System memo issued on November 14, 2014, we encouraged sponsors to remove the beneficiary-level prior authorization (PA) edits on these drugs. When claims are submitted to Part D for drugs in the seven categories, we expect that they are not being used for the treatment of ESRD and, therefore, may be coverable under

Part D. We also expect that Medicare ESRD facilities will continue to provide all of the medications used for the treatment of ESRD, including drugs in the seven categories. We will continue to monitor the utilization of renal dialysis drugs and biologicals under Part B and Part D.

b. Oral or Other Forms of Renal Dialysis Injectable Drugs and Biologicals

The ESRD PPS includes certain drugs and biologicals that were previously paid under Part D. Oral or other forms of injectable drugs and biologicals used for the treatment of ESRD, for example, vitamin D analogs, levocarnitine, antibiotics or any other oral or other form of a renal dialysis injectable drug or biological are also included in the ESRD PPS and may not be separately paid. These drugs are included in the ESRD PPS payment because the payments made for both the injectable and oral forms were included in the ESRD PPS base rate. As discussed in section II.B.4.of this final rule, implementation of oral-only drugs used in the treatment of ESRD (that is, drugs with no injectable equivalent) under the ESRD PPS payment has been delayed until 2025.

In the CY 2011 ESRD PPS final rule (75 FR 49172), we stated that ESRD facilities are required to record the quantity of oral medications provided for the monthly billing period. In addition, ESRD facilities would submit claims for oral drugs only after having received an invoice of payment. We indicated that we would address recording of drugs on an ESRD claim in future guidance. We included this requirement because renal dialysis drugs and biologicals that were paid separately prior to the ESRD PPS, as many of these oral medications were, are eligible outlier items and services. If an ESRD facility were to report a 90-day supply of a drug on a monthly claim, the claim could receive an outlier payment erroneously.

On June 7, 2013, we issued an update to the Medicare Benefits Policy Manual, Pub. 100–02, Chapter 11 to reflect implementation of the ESRD PPS in Change Request 8261.In section 20.3.C of the updated Medicare Benefits Policy Manual, we stated that for ESRD-related oral or other forms of drugs that are filled at the pharmacy for home use, ESRD facilities should report one line item per prescription, but only for the quantity of the drug expected to be taken during the claim billing period.

Example: A prescription for oral vitamin D was ordered for one pill to be taken 3 times daily for a period of 45 days. The patient began taking the medication on April 15, 2011. On the April claim, the ESRD facility would report the appropriate National Drug Code (NDC) code for the drug with the quantity 45 (15 days × 3 pills per day). The remaining pills which would be taken in May would appear on the May claim for a quantity of 90 (30 days × 3 pills per day). Prescriptions for a 3 month supply of the drug would never be reported on a single claim. Only the amount expected to be taken during the month would be reported on that month's claim.

In February 2015, we were informed by one of the large dialysis organizations that they, and many other ESRD chain organizations, are out of compliance with the requirement that only the quantity of the drug expected to be taken during the claim billing period should be indicated on the ESRD monthly claim. They indicated that some facilities are incorrectly reporting units that reflect a 60-day or 90-day prescription while other facilities are not reporting the oral drugs prescribed. The reason given for these reporting errors is the lack of prescription processing information. Specifically, while the facilities know when the pharmacy fills the prescription, they do not know when the patient picks up the drug from the pharmacy and begins to take the drug.

Due to this confusion and lack of compliance, we are reiterating our current policy that all renal dialysis service drugs and biologicals prescribed for ESRD patients, including the oral forms of renal dialysis injectable drugs, must be reported by ESRD facilities and the units reported on the monthly claim must reflect the amount expected to be taken during that month. The facilities should use the best information they have in determining the amount expected to be taken in a given month, including fill information from the pharmacy and the patient's plan of care. Any billing system changes to effectuate this change must be made as soon as possible as this requirement has been in effect since the ESRD PPS began in 2011. We are analyzing ESRD facility claims data to determine the extent of the reporting error and may take additional actions in the future.

We received the following comment on the clarification which is described below.

Comment: A patient advocacy group requested that CMS change its requirement that the monthly claim submitted by ESRD facilities only report the ESRD-related oral drugs expected to be taken during the month. They believe it is burdensome to ESRD facilities to compute the amount of pills prescribed to a patient within the claim period, especially for smaller facilities, whose limited resources make this type of data manipulation more arduous. They noted that this requirement diverts resources away from patient care.

Response: Unfortunately, we are unable to revise the billing requirements as the commenter suggests. ESRD facilities submit a monthly bill, which needs to include only the items and services utilized during the month. Under the outlier policy, we sum the MAP amounts for the outlier services on the claim to assess whether that amount exceeds the predicted outlier services MAP amount plus the fixed dollar loss amount. If an ESRD facility were to report a 90-day supply of a drug on a monthly claim, the claim could receive an outlier payment erroneously.

c. Reporting of Composite Rate Drugs

As we indicate in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 8, section 50.3, as revised by Change Request 8978, issued December 2, 2014, in an effort to enhance the ESRD claims data for possible future refinements to the ESRD PPS, CMS announced that ESRD facilities should begin reporting composite rate drugs on their monthly claims. Specifically, ESRD facilities should only report the composite rate drugs identified on the consolidated billing drug list and provided below in Table 11.

TABLE 11—COMPOSITE RATE DRUGS AND BIOLOGICALS

Composite Rate Drugs and Biologicals	A4802	INJ PROTAMINE SULFATE
	J0670	INJ MEPIVACAINE HYDROCHLORIDE
	J1200	INJ DIPHENHYDRAMINE HCL
	J1205	INJ CHLOROTHIAZIDE SODIUM
	J1240	INJ DIMENHYDRINATE
	J1940	INJ FUROSEMIDE
	J2001	INJ LIDOCAINE HCL FOR INTRAVENOUS INFUSION, 10 MG
	J2150	INJ MANNITOL
	J2720	INJ PROTAMINE SULFATE
	J2795	INJ ROPIVACAINE HYDROCHLORIDE
	J3410	INJ HYDROXYZINE HCL
	J3480	INJ. POTASSIUM CHLORIDE, PER 2 MEQ.
	Q0163	DIPHENHYDRAMINE HYDROCHLORIDE

The ESRD PPS payment policy remains the same for composite rate drugs, therefore, no separate payment is made and these drugs will not be designated as eligible outlier services. This information will provide CMS with the full scope of renal dialysis services which may better target outlier services to the most costly patients. We did not receive any comments on the clarification of reporting composite rate drugs and biologicals.

III. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year

A. Background

For more than 30 years, monitoring the quality of care provided by dialysis facilities to patients with end-stage renal disease (ESRD) has been an important component of the Medicare ESRD payment system. The ESRD Quality Incentive Program (QIP) is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by CMS. The ESRD QIP is authorized by section 1881(h) of the Social Security Act (the Act), which was added by section 153(c) of the Medicare Improvements for Patients and Providers Act (MIPPA).

Section 1881(h) of the Act requires the Secretary to establish an ESRD QIP by (1) selecting measures; (2) establishing the performance standards that apply to the individual measures; (3) specifying a performance period with respect to a year; (4) developing a methodology for assessing the total performance of each facility based on the performance standards with respect to the measures for a performance period; and (5) applying an appropriate payment reduction to facilities that do not meet or exceed the established Total Performance Score (TPS). This final rule discusses each of these elements and our policies for their application to PY 2017, PY 2018, PY 2019, and future years of the ESRD QIP.

We received comments about general policies and principles of the ESRD QIP. The comments and our responses are set forth below.

Comment: Two commenters argued that ESRD QIP standards often prevent improved patient outcomes by being a roadblock to the conduct of clinical trials which, commenters argued, are critically important in the quest for advancement of quality care for patients with ESRD. They added that exemption from certain performance standards and/or quality measures should be available for those patients who are involved in clinical trials, particularly when they involve evidence gathering to promote improved patient outcomes. One commenter specifically recommended that any patients entered into such a trial be exempted from the vascular access measure topic, which assesses the percentage of patients with catheters versus the percentage of patients with fistulas so that their providers can participate in the trial

without fear of being penalized under the ESRD QIP.

Response: We thank commenters for their recommendation and will consider the appropriateness of the ESRD QIP requirements for participation and exceptions thereto for future years of the program.

Comment: A few commenters expressed concerns with the way CMS releases ESRD QIP data. One commenter requested that CMS make all data used in developing proposed rules available at the time the proposed rule is published and another expressed concerns with the format and timing of data releases.

Response: We seek to be as transparent as possible and have released all analyses that we took into consideration in the development of the proposed rule. In addition, we published a public use data file at the same time as the proposed rule for the ESRD QIP that contains the facility-level data used to calculate the performance standards, achievement thresholds, and benchmarks we proposed for the program. These public use files are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/08_ReportandCert.html.* Furthermore, in response to comments received during the notice-and-comment process, we have conducted additional analyses and are describing those results in this final rule and on the CMS Web site, as well as making the details of these additional analyses available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html.*

Comment: Commenters recommended that CMS focus on stabilizing the existing policies and measures in the ESRD QIP before adopting any new measures. They expressed concern that constantly increasing the measure set's size and complexity gives facilities little time to implement new policies and procedures for data collection and reporting while also providing high quality care on a daily basis. One commenter argued that as the number of measures increases, so too do costs to providers and to CMS. They stated that the QIP should strive to include, to the extent feasible, those measures which address multiple domains of CMS's value-based purchasing programs and are not duplicative.

Response: Although we recognize that adopting more measures in the ESRD QIP increases costs to facilities as well as to CMS, we believe these increased costs are outweighed by the benefits to patients of incentivizing quality care in the domains that the measures cover. We agree that adopting measures that span multiple domains, such as the SRR clinical measure, allows us to address multiple aspects of quality, reduces the total number of measures in the ESRD QIP, and presents less burden for facilities than adopting multiple measures that each address a single domain. Going forward, we will continue to strive to ensure that the ESRD QIP measure set is as parsimonious as possible.

Comment: One commenter requested information regarding the claims that we used to calculate facility performance on the dialysis adequacy clinical measures for the PY 2016 ESRD QIP.

Response: For PY 2016, CY 2014 Medicare outpatient dialysis claims (bill type 72) were used to calculate the dialysis adequacy measures. These claims data were extracted from CMS systems on April 24, 2015 and included all fully adjudicated claims submitted by facilities that were in final action status [2] as of that date.

Comment: One commenter requested clarification on how the ESRD QIP accounts for patients who switch modality mid-month for measures collected using CROWNWeb.

Response: For PY 2016 there was no distinction made between hemodialysis and peritoneal dialysis patients with regard to the serum calcium and serum phosphorus values reported in CROWNWeb, which is consistent with the specifications for the Hypercalcemia clinical measure. All clinical values submitted under either modality were reviewed and the last clinical value submitted for each month was used for the calculation of the Hypercalcemia measure. The Mineral Metabolism reporting measure considers the aggregate modality during a month, as defined by the patient's Medicare claims, to determine patient eligibility for the month. If the aggregate modality is in-center hemodialysis and the patient was not treated at least seven times during the month and then changes modality to peritoneal dialysis to home hemodialysis, the patients would be excluded. However, if the patient switches from in-center hemodialysis to peritoneal dialysis or home hemodialysis and the aggregate modality is either home hemodialysis or peritoneal dialysis, the patient would be included in the measure. Regardless of the modality listed on a patient's claims, any serum phosphorus value reported as either a peritoneal dialysis or home hemodialysis in CROWNWeb would count as an eligible serum phosphorus value, but if a patient switched modalities during the month, it could impact their eligibility for that month. The Pain Assessment and Follow-Up and Screening for Clinical Depression and Follow-Up Reporting Measures, which are also collected using CROWNWeb, do not account for a patient's treatment modality in their scoring calculations.

Comment: One commenter requested that only Medicare-based measure data be used to calculate performance scores impacting Medicare payments.

Response: Although payment reductions under the ESRD QIP are made to a facility's Medicare ESRD reimbursement amounts, in order to properly assess whether Medicare beneficiaries are receiving the same quality of care as other patients, we believe it is appropriate to collect, where possible, all-patient data.

Comment: One commenter urged CMS to create more alignment among its quality programs. The goals of the ESRD QIP, DFC, and the Conditions for Coverage are all designed to ensure the best possible outcomes for patients but when the programs do not align, the commenter argued, facilities are confused and are not as well equipped to meet the demands of the separate programs.

Response: We agree with the goal of creating more alignment among CMS's quality programs. As stated previously in the CY 2015 final rule with comment period (79 FR 66162), the goals of the ESRD QIP closely align with the goals of the CMS Quality Strategy (the CMSQS), which all CMS quality improvement efforts are structured around, including DFC and the ESRD Conditions for Coverage. The CMSQS is designed to guide the activities of various components throughout the Agency and is aligned with the Department of Health and Human Services' (HHS') National Quality Strategy (the NQS). The six goals of the CMSQS—(1) Make care safer by reducing harm caused in the delivery of care; (2) strengthen person and family engagement as partners in their care; (3) promote effective communication and coordination of care; (4) promote effective prevention and treatment of chronic disease; (5) work with communities to promote best practices of healthy living; and (6) make care affordable—are organized around NQS's three broad aims of Better Care; Affordable Care; and Healthy People, Healthy Communities and drive and

[2] A claim is considered to be in final action status when it reflects services billed by the facility for facility costs, has been processed by the Medicare Administrative Contractor, has been resubmitted and corrected if necessary, and has been finalized.

orient all of CCSQ's quality improvement programs, including the ESRD QIP, insofar as these aims align with the statutory goals of the program.

The strategic vision of the ESRD QIP is to adopt measures that address each of these goals. The following table illustrates the program's efforts to implement this strategic vision:

TABLE 12—CMSQS GOAL AND ESRD QIP MEASURE ALIGNMENT

CMSQS goal	Measure
Promote effective prevention and treatment of chronic disease	Dialysis Adequacy. Vascular Access Type Measure Topic: Fistula. Catheter for at Least 90 Days. Mineral Metabolism Reporting. Anemia Management Reporting. Hypercalcemia. Standardized Transfusion Ratio. Screening for Depression and Follow Up reporting. Pain Assessment and Follow-Up reporting.
Strengthen person and family engagement as partners in their care	ICH CAHPS Reporting (PY 2017) and clinical (PY 2018).
Promote effective communication and coordination of care	Standardized Readmissions Ratio.
Make care safer by reducing harm caused in the delivery of care	NHSN Bloodstream Infection in Hemodialysis Outpatients. NHSN Healthcare Personnel Influenza Vaccination reporting.
Work with communities to promote best practices of healthy living	None.
Making care affordable	None.

As the table above illustrates, the ESRD QIP has not adopted measures for the following quality goals:

- Work with communities to promote the best practices of healthy living.
- Making care affordable.

We will evaluate these remaining goals, particularly the goal of making care affordable, to assess their appropriateness as policy goals for the ESRD QIP. In addition to evaluating the ESRD QIP measure set in terms of how well it addresses legislative mandates, NQS and CMSQS goals, we are also evaluating how well the measure set addresses policy priorities that stakeholders have brought to our attention. We continue to engage both external and internal stakeholders on a regular basis, to communicate the strategic vision of the program as well as to engage in dialogue useful to the development and implementation of policy that will effectively create improvements in the quality of care provided to ESRD beneficiaries.

Comment: One commenter requested that CMS provide a clear definition of when patients are no longer considered ESRD and are therefore excluded from measure calculations.

Response: For claims-based measures, if a facility submits a Medicare outpatient dialysis facility claim (bill type 72) for treatment provided to a patient, then the patient is considered to be on chronic dialysis. Patients are not included in a claims-based measure calculation for a month if a claim is not submitted for the patient for treatment received that month.

For the SRR and STrR measures, details regarding the determination of a patient's time on dialysis and patient attribution to a facility can be found in the ''Report for the Standardized Readmission Ratio'' and ''Report for the Standardized Transfusion Ratio'', respectively (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/MeasureMethodologyReportfortheProposedSRRMeasure.pdf; https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/MeasureMethodologyReportfortheProposedSTrRMeasure.pdf*). Finally, for CROWNWeb measures, if a patient is admitted to the facility during the month, the patient is considered to be eligible for the measure calculation until the patient is discharged. Depending on the measure, a patient may be required to be admitted to the facility for the entire reporting month in order to be included in that patient-month. We encourage commenters to review the measure specifications available on the CMS Web site for more information (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*).

Comment: Several commenters recommended that CMS work with the kidney community to establish a patient-centric vision for quality that aims to decrease mortality, decrease hospitalizations, increase patient satisfaction, and improve patient experience with care.

Response: We thank the commenters for their recommendation and support of collaboration between CMS and the ESRD community. We note that the ESRD QIP maintains measures that aim to decrease hospitalizations (the Standardized Readmission Ratio clinical measure) and increase patient satisfaction and experience with care (the ICH CAHPS clinical measure), and Dialysis Facility Compare maintains a Standardized Mortality Ratio measure. As such, we continue to engage both internal and external stakeholders on a regular basis, to communicate the strategic vision of the Program as well as to engage in dialogue useful to the development and implementation of policy that will effectively create improvements in the quality of care provided to ESRD patients.

Comment: One commenter recommended that CMS consider adopting the following major tenets: (1) Continued transparency and collaboration in measure development and specifications; (2) parsimony in the QIP and other programs that comparatively assess quality of care performance; (3) avoidance of incentives that may undermine the delivery of individualized patient care to obtain a more favorable QIP score; and (4) recognizing promptly when a measure is topped out, either clinically or statistically, to avoid unintended consequences, including loss of the ability to individualize care, pressure to provide care that may not be in the best interests of an individual patient and/or diverting attention from other measures that may be better targets for quality improvement.

Response: We thank the commenter for its recommendations and we agree with the general principles expressed. We also already consider these tenets in

the development and refinement of the ESRD QIP. We seek to collaborate with measure developers on measures and specifications and we continue to seek ways to increase transparency. One example of this is the Measures Manual, currently in development and discussed more fully below, which will compile the technical measure specifications of ESRD QIP and Dialysis Facility Compare measures in a single resource that is easy to use. We are also developing a mechanism that will allow stakeholders to recommend refinements to ESRD QIP measures based on their clinical experience.

We also seek parsimony in the QIP and other programs that comparatively assess quality of care. We continue to assess the negative unintended consequences of measures and policies maintained by the ESRD QIP through efforts such as the Access to Care study in an effort to incentivize the delivery of individualized patient care, and will continue to do so. Finally, in the CY 2015 ESRD PPS final rule with comment period (79 FR 66171 through 66174), we developed a set of statistical criteria for determining when a measure is ''topped out'' and may therefore be eligible for removal from the ESRD QIP. We look forward to continued collaboration with the ESRD community to achieve each of these goals.

Comment: One commenter emphasized the importance of ensuring that all patients are educated about their treatment options and where to get them, and recommended that CMS require the use of a values-based, patient-centered dialysis decision aid for patients. The commenter explained that such a tool would ensure patients have the opportunity to match their values to the varying treatment options and choose a treatment that is a good fit for their lifestyles and preferences.

Response: We agree that it is important for patients to be educated about their treatment options and where various treatments may be available. Dialysis treatment is a highly individualized process of care; we therefore strongly encourage nephrologists and dialysis facilities to discuss treatment options with their patients on an ongoing basis to account for changes in the patient's health and experience with dialysis treatment.

Comment: One commenter urged CMS to consider adopting a bifurcated quality reporting and value based purchasing program for ESRD similar to those we have implemented for the Hospital VBP and Hospital Inpatient Quality Reporting Programs.

Response: We thank commenters for their recommendation and note that we currently adopt some ESRD QIP measures as reporting measures prior to assessing performance on those measures as clinical measures.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year (PY) 2019 Proposed Rule

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program'' (80 FR 37807 through 37860), (hereinafter referred to as the CY 2016 ESRD PPS proposed rule), was published in the **Federal Register** on July 1, 2015, with a comment period that ended on August 25, 2015. In that proposed rule, for the ESRD PPS, we proposed routine updates to the End-Stage Renal Disease Quality Incentive Program, proposed to adopt new measures the PY 2019 ESRD QIP measure set, and proposed to revise the small facility adjuster (SFA) used in facility scoring for the program. We received approximately 37 public comments on our proposals, including comments from: ESRD facilities, national renal groups, nephrologists and patient organizations, patients and care partners, manufactures, health care systems, and nurses.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ESRD QIP. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

C. Clarification of ESRD QIP Terminology: ``CMS Certification Number (CCN) Open Date''

Some stakeholders have expressed confusion about the use of the term ''CMS Certification Number (CCN) Open Date'' under the ESRD QIP (for example, see 79 FR 66186). We interpret this term to mean the ''Medicare effective date'' under 42 CFR 489.13, which governs when the facility can begin to receive Medicare reimbursement for ESRD services under the ESRD PPS. Thus, a facility is eligible, with respect to a particular payment year, to receive scores on individual measures and participate in general in the ESRD QIP based on the facility's CCN Open Date (that is, Medicare effective date).

We received comments on this clarification. The comments and our responses are set forth below.

Comment: Many commenters supported our clarification of the term, ''CMS Certification Number (CCN) Open Date,'' and appreciated this clarification. One commenter added that once a facility is eligible to receive payment under the ESRD PPS, it should also be eligible to participate in the ESRD QIP.

Response: We thank the commenters for their support and are pleased that this clarification will reduce confusion for facilities moving forward. We note that facility eligibility to receive payment under the ESRD PPS is also keyed to a facility's CCN Open Date; therefore, facilities are eligible to receive payment under the ESRD PPS at the same time as they become eligible to participate in the ESRD QIP.

D. Use of the Hypercalcemia Measure as a Measure Specific to the Conditions Treated with Oral-Only Drugs

Section 217(d) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93), enacted on April 1, 2014, amends section 1881(h)(2) of the Act to require the Secretary to adopt measures in the ESRD QIP (outcomes based, to the extent feasible) that are specific to the conditions treated with oral-only drugs for 2016 and subsequent years. We stated in the CY 2015 ESRD PPS final rule (79 FR 66168–69) that we believed the Hypercalcemia clinical measure, which was adopted beginning with the PY 2016 program meets this new statutory requirement; nevertheless, we also recognized that, consistent with PAMA, we could adopt measures as late as for CY 2016, which would be included in the PY 2018 ESRD QIP. We also stated that we would take into account comments on whether the Hypercalcemia clinical measure can be appropriately characterized as a measure specific to the conditions treated with oral-only drugs.

Although section 1881(h)(2)(E)(i) does not define the term ''oral-only drugs,'' we have previously interpreted that term to mean ''drugs for which there is no injectable equivalent or other form of administration'' (75 FR 49038). We have also previously identified calcimimetics and phosphate binders as two types of ''oral-only drugs'' (75 FR 49044).

We are currently aware of three conditions that are treated with calcimimetics and phosphate binders: Secondary Hyperparathyroidism, Tertiary Hyperparathyroidism, and Hypercalcemia. Hypercalcemia is a condition that results when the entry of calcium into the blood exceeds the excretion of calcium into the urine or

deposition in bone; the condition may be caused by a number of other conditions, including hyperparathyroidism. Although multiple treatment options are available for patients with early forms of hypercalcemia, calcimimetics are frequently prescribed for those patients who develop hypercalcemia secondary to tertiary hyperparathyroidism, in order to most easily control the patients' serum calcium levels. Because hypercalcemia is a condition that is frequently treated with calcimimetics, and because calcimimetics are oral-only drugs, we believe that the current Hypercalcemia clinical measure (NQF #1454) meets the requirement that the ESRD QIP measure set include for 2016 and subsequent years measures that are specific to the conditions treated with oral-only drugs.

We acknowledge that the Hypercalcemia clinical measure is not an outcome-based measure, and we have considered the possibility of adopting outcome-based measures that are specific to the conditions treated with oral-only drugs. However, we are currently not aware of any outcome-based measures that would satisfy this requirement. We welcomed comments on whether such outcome-based measures are either ready for implementation now or are being developed, and we intend to consider the feasibility of developing such a measure in the future.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Many commenters did not support use of the Hypercalcemia clinical measure to satisfy the requirements of PAMA. Some commenters stated that CMS's rationale for using this measure is that calcimimetics are oral-only agents commonly used to treat hypercalcemia. The commenters argued however, that only ⅓ of ESRD patients are prescribed a calcimimetic, and noted that, while it is true that the pharmacologic mechanism of calcimimetics results in lower serum calcium, they are not in fact FDA-approved to treat hypercalcemia in patients with secondary hyperparathyroidism. The commenters maintained that hypercalcemia in ESRD patients is commonly due to the receipt of Vitamin D analogs, which are not oral-only agents. Commenters also noted that the treatment of hypercalcemia commonly includes reducing or discontinuing vitamin D analogs in addition to decreasing the dialysate calcium concentration. One commenter did not support CMS' position that the Hypercalcemia clinical measure meets the requirements of PAMA because the measure only assesses calcium lab values, which are not the most accurate indicator of care for patients prescribed oral-only drugs. Another commenter argued that the Hypercalcemia clinical measure does not satisfy the requirements of PAMA because hypercalcemia may be treated with drugs other than oral-only drugs, including bisphosphonates, IV fluids and diuretics.

Response: We thank the commenters for their comments. We note that the KDIGO clinical practice guidelines recommend maintenance of CKD 3–5D patient's serum calcium in the normal range. This was recognized by the C–TEP members that developed the Hypercalcemia clinical measure in 2010 and other clinical experts (NQF subcommittee and 2013 C–TEP) who reviewed that measure and agreed with the basic justification for the measure that some treatments used to treat hyperparathyroidism have been shown to cause hypercalcemia. Furthermore, clinical concerns about the use of calcium-containing phosphorus binders have been raised by some in the dialysis community related to risk for hypercalcemia and calcium-related vascular mineralization. Hypercalcemia is seen as a potentially dangerous consequence of such treatments, based on a growing laboratory experimental literature and clinical paradigm that points to vascular calcification as an emerging non-traditional risk factor for vascular disease in this population. This emerging paradigm and concerns about unintended consequences of use of vitamin D sterols to treat hyperparathyroidism are reflected in the KDIGO guideline that specifically recommends reduction or discontinuation of vitamin D therapy in patients who develop hypercalcemia.

The alternative to use of vitamin D sterols for treatment of hyperparathyroidism is cinacalcet, a calcimimetic agent approved for treatment of secondary hyperparathyroidism. As noted in the package insert for cinacalcet, lower serum calcium and even hypocalcemia have been noted with cinacalcet use, demonstrating the complex interplay between alternative drugs used to treat hyperparathyroidism and hyperphosphatemia, and the role of these drugs in the development and treatment of hypercalcemia and hyperparathyroidism.

In addition, although we agree that hypercalcemia may also be treated with drugs that are not oral-only drugs, including bisphosphonates, IV fluids and diuretics, we do not interpret section 217(d) of PAMA as requiring the Secretary to adopt measures which are specific to the conditions treated *only* with oral-only drugs. Because hypercalcemia can be treated with calcimimetics, an oral-only drug, we continue to believe that the hypercalcemia clinical measure satisfies the requirements of PAMA.

We also note that limitations in available evidence have, thus far, prevented us from developing measures that might address oral-only medications that are more broadly used in the ESRD dialysis population. In 2010, a Technical Expert Panel discussed the possibility of developing measures for phosphorous, but was unable to come to a consensus regarding a phosphorus measure that assesses appropriate levels of phosphorous due to a lack of evidence supporting a clinical threshold. A process measure was developed and originally endorsed by the NQF in 2007, and is the measure on which the current Mineral Metabolism reporting measure is based. However, as explained below, we believe that the Mineral Metabolism measure is limited because it only assesses the reporting of phosphorus values, rather than assessing performance based on the values themselves. In addition, the Mineral Metabolism reporting measure does not meet the requirements of PAMA because this measure, as adopted for the ESRD QIP, is not NQF-endorsed or adopted by another consensus-based entity with expertise in kidney disease. In 2011, NQF reviewed one measure with an upper limit (hyperphosphatemia) and one measure with a lower limit (hypophosphatemia), but did not endorse either measure. A recent 2013 Technical Expert Panel recommended the development of a reporting measure for PTH. However, the panel concluded that there was insufficient evidence to develop a clinical intermediate outcome measure with a target PTH value. We are unaware of more recent evidence suggesting that a new measure meeting the requirements of PAMA will be available in the near future, but are interested in discussing any such evidence with stakeholders.

As the state of clinical evidence evolves to support additional, more comprehensive measures of mineral bone disease, we look forward to continued consultation with the dialysis community.

Comment: A number of commenters did not support the use of the Hypercalcemia clinical measure to satisfy the requirements of PAMA based

on belief that the measure does not provide value to the patient, relate to the provision of quality care, or adequately reflect the complexity of bone and mineral disorders. They also noted that the NQF Renal Steering Committee initially recommended against endorsement for the Hypercalcemia clinical measure during its May, 2015 meeting. Several commenters also encouraged CMS to work with experts in the kidney community to develop a composite measure evaluating phosphorus, calcium, and parathyroid hormone levels because such a measure would be more likely to improve patient outcomes than multiple individual measures. Specifically, they recommended that CMS convene a TEP to develop a measure, which can be submitted for endorsement by NQF, and which would satisfy the statutory and regulatory requirements. Other commenters recommended the adoption of individual measures on serum phosphorus management, hyperphosphatemia, and medication reconciliation.

Response: Although the Hypercalcemia clinical measure does not assess all of the hormone levels mentioned by the commenters, we believe this measure assesses an important aspect of ESRD patients' care because abnormalities of bone mineral metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced chronic kidney disease. We also believe that the measure relates to the provision of quality care furnished to patients by facilities because issues related to bone mineral metabolism have serious health consequences for patients with ESRD. As discussed above, we would welcome the opportunity to work with stakeholders to develop a more comprehensive measure that meets the requirements of PAMA.

Comment: One commenter did not support the use of the Hypercalcemia clinical measure to satisfy the requirements of PAMA because they believe that an isolated metric to avoid hypercalcemia could have the unintended consequence of leading to a decrease in utilization of vitamin D analogs and calcium-containing phosphate binders, which might result in worsening the incidence of hyperparathyroidism and hyperphosphatemia in ESRD patients.

Response: We agree that it would be beneficial to adopt a more comprehensive mineral bone disease measure, but as explained above, we are currently unaware of any measure on this topic.

Comment: One commenter recommended CMS convene a Technical Expert Panel on oral-only drugs to spur development of a more appropriate measure on this topic.

Response: We thank the commenter for its recommendation, and we intend to examine opportunities to convene a TEP specific to conditions treated using oral-only drugs.

Comment: One commenter recommended that CMS use the current Mineral Metabolism reporting measure to satisfy the requirements of PAMA because hypercalcemia is an incomplete proxy for monitoring conditions currently treated with oral-only drugs. The commenter further noted that a larger proportion of ESRD patients are treated with oral phosphate binder therapy for hyperphosphatemia than with calcimimetics for hypercalcemia.

Response: We note that the Mineral Metabolism reporting measure assesses facilities reporting phosphorous values, not the values themselves. Furthermore, previous attempts to develop measures for phosphorous in 2010 and 2011 were unsuccessful because consensus was not reached regarding an appropriate level of phosphorous due to lack of clinical evidence. We therefore believe that the Hypercalcemia clinical measure is a superior measure of bone mineral metabolism at this time. In addition, the Mineral Metabolism reporting measure does not meet the requirements of PAMA because this measure, as adopted for the ESRD QIP, is not NQF-endorsed or adopted by another consensus-based entity with expertise in kidney disease.

E. Sub-Regulatory Measure Maintenance in the ESRD QIP

In the CY 2013 ESRD PPS final rule, we finalized our policy to use a sub-regulatory process to make non-substantive updates to measures (77 FR 67477). We currently make available the technical specifications for ESRD QIP measures at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html* but are in the process of drafting a CMS ESRD Measures Manual which will include not only the ESRD QIP measure specifications, but also technical information on quality indicators that facilities report for other CMS ESRD programs. We expect to release the first version of the CMS ESRD Measures Manual in the near future at the following web address: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/index.html.* The manual will be released before the beginning of the applicable performance period, preferably at least 6 months in advance. We believe that this update frequency will be sufficient to provide facilities with information needed to incorporate these updates into their ESRD data collection activities. We note that this policy is consistent with our policy for updating the CMS National Hospital Inpatient Quality Measures Specifications Manual, which is posted on the QualityNet Web site (*www.qualitynet.org*).

We welcomed recommendations from the public on technical updates to ESRD QIP measures. We will consider the appropriateness of all recommendations, notify those who submit recommendations as to whether we accept the recommendation, and incorporate accepted recommendations in a future release of the CMS ESRD Measure Manual. At present, we intend to use JIRA, a web-based collaboration platform maintained by the Office of the National Coordinator for Health Information Technology, to receive, consider, and respond to recommendations for non-substantive measure changes. Further information about how to use the JIRA tool to make such recommendations will be published in an upcoming CROWN Memo and will be posted to *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/index.html.*

The comments and our responses are set forth below.

Comment: Many commenters supported CMS's development of an ESRD Measures Manual as an important step in increasing transparency and understanding of the ESRD measures. They also supported our intended use of the JIRA system to accept feedback and suggestions from stakeholders and also recommended that CMS include contact information for Agency staff so that dialysis providers have a point-of-contact within the Agency who can answer questions regarding the interpretation of measures. One commenter added that the Manual should not replace traditional notice-and-comment rulemaking with respect to measure details, but should instead serve as a document for aggregating technical specifications and implementation rules for all ESRD quality measures. One commenter recommended that CMS make the measure micro-specifications and other technical information part of the rulemaking process to ensure commenters fully understand measure proposals.

Response: We thank commenters for their support and we agree that the ESRD Measures Manual is an important step in increasing transparency and understanding of the ESRD measures as they are currently specified for use in the ESRD QIP and/or DFC. Although we intend to use JIRA as the sole means by which stakeholders communicate with us regarding the measures (outside of the rulemaking process), we will seek to ensure this process is as transparent as possible. The Manual will gather in one resource all measure specifications, including what we refer to as micro-specifications (additional technical details regarding the complexities of calculating measure scores), that are currently made available through separate resources. The Measures Manual will create an additional vehicle for communication and discussion of measure specifications, but will not replace the traditional notice-and-comment rulemaking process, or our policy to use rulemaking to adopt substantive updates to measures. Rather, the Measures Manual will be used to implement technical updates to measures, many of which can be suggested by stakeholders through JIRA. Consistent with our current policy, we will also provide notice of technical updates through CROWN Memos and other means of communication.

Comment: One commenter specifically requested that CMS make available additional detail about the STrR measure's technical specifications in the ESRD Measures Manual, along with detailed flowcharts or computer codes so that the public can replicate the mathematics used, and asked that these be provided prior to adopting any measures in future years of the QIP.

Response: The upcoming Measures Manual will include all necessary information to calculate measure scores for all clinical measures, including the STrR clinical measure. We encourage stakeholders to review and submit comments on the Measures Manual in order to ensure its responsiveness to stakeholder needs.

F. Revision to the Requirements for the PY 2017 ESRD QIP

1. Modifying the Small Facility Adjuster (SFA) Calculation for All Clinical Measures Beginning With the PY 2017 ESRD QIP

In the CY 2013 ESRD PPS final rule we adopted a scoring adjustment for facilities with relatively small numbers of patients, called the small facility adjuster, which aims to ensure that any error in measure rates due to a small number of cases will not adversely affect facility payment (77 FR 67511). Since we first implemented the methodology to implement the small facility adjuster, we have encountered two issues related to basing the adjustment on the within-facility standard error. First, facility scores for some of the outcome measures adopted in the ESRD QIP, such as the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical measure, do not approximate a normal or ''bell-shaped'' distribution. In such cases, the within-facility standard error does not necessarily capture the spread of the data as it would if facility scores were normally distributed. Second, facilities and other stakeholders have commented that it is difficult for them to independently calculate pooled within-facility standard errors because doing so requires data for all patient-months across all facilities, which makes the small facility adjuster unnecessarily opaque. For these reasons, we have developed an equation for determining the small facility adjuster that does not rely upon a within-facility standard error, but nonetheless preserves the intent of the adjuster to include as many facilities in the ESRP QIP as possible while ensuring that the measure scores are reliable.

Therefore, beginning with the PY 2017 ESRD QIP, we proposed to use the following methodology to determine the small facility adjustment:

- For the i^{th} facility, suppose the facility's original measure rate is p_i and the number of patients (or other unit used to establish data minimums for the measure. For example, index discharges for the Standardized Readmission Ratio clinical measure) at the i^{th} facility is n_i.
- Where the number of eligible patients (or other appropriate unit) needed to receive a score on a measure is L and the upper threshold for applying the small facility adjuster is C, the i^{th} facility will be eligible for the adjustment when $L \leq n_i \geq C$. Accordingly, L and C set the upper and lower thresholds of eligible patients (or other appropriate unit) a facility needs to have in order to be considered for a small facility adjustment; consistent with previously finalized policies, facilities with fewer than L eligible patients (or other appropriate unit) for a measure will not receive a score on that measure, and facilities with more than C eligible patients (or other appropriate unit) for a measure will not receive an adjustment for that measure.
- Assuming $L \leq n_i < C$, let $w_i = n$, where n_i is the number of patients (or other appropriate unit) at the i^{th} facility and C is the upper thresholds of eligible patients (or other appropriate unit) a facility needs to have in order to be considered for a small facility adjustment. This calculation will produce the facility's weighting coefficient for a given clinical measure, w_i, which provides a metric for assessing the uncertainty due to small facility sizes.
- For measures where higher scores are better (for example, the Vascular Access Type (VAT): Fistula clinical measure and the Dialysis Adequacy clinical measures), a small facility's adjusted performance rates (t_i) will be pegged to the national mean performance rate ($\overline{P}$) as follows:
  - If $p_i < \overline{P}$, then $t_i = w_i * p_i + (1 - w_i * \overline{P}$,
  - If p_i is greater than or equal to $\overline{P}$, the facility will not receive an adjustment.
- For measures where lower scores are better (for example, VAT: Catheter, NHSN BSI, Hypercalcemia, Standardized Readmission Ratio (SRR), and Standardized Transfusion Ratio (STrR) clinical measures), a small facility's adjusted performance rates (t_i) will be pegged to the national mean performance rate ($\overline{P}$) as follows:
  - If $p_i > \overline{P}$, then $t_i = w_i * p_i + (1 - w_i * \overline{P}$
  - If p_i is less than or equal to $\overline{P}$, then the facility will not receive an adjustment
- For the standardized ratio measures, such as the SRR and STrR clinical measures, the national mean measure rate (that is, $\overline{P}$) is set to 1.

We note that the equation $t_i = w_i * p_i + (1 - w_i) * \overline{P}$ is designed to ''shrink'' the facility mean toward the national mean, and that reflects the degree of confidence in the estimation of the facility mean, because it depends on facility size. Some research has shown that this type of ''shrinkage estimator'' equation gives a small mean squared error (that is, the combination of bias and variance) if the national mean truly reflects the performance of a small facility, which was the intention of the equation.[3]

To assess the impact of the proposed small facility adjuster, we conducted an impact analysis of this proposed methodology on individual measure scores and facility TPSs, using the final dataset used to calculate PY 2015 ESRD QIP scores. The full results of this analysis can be found at *https://www.cms.gov/Medicare/Quality-*

[3] Efron B, Morris C. Empirical Bayes on vector observations: An extension of Stein's method. *Biometrika,* 59(2):335–347. Ahmed SE., Khan SM. Improved estimation of the Poisson parameter. *Statistica,* anno LIII n.2, 268–286, 1993. Ahmed SE. Combining Poisson means. *Communications in Statistics: Theory and Methods,* 20, 771–789, 1991.

Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Small-Facility-Adjustment-Proposal-for-the-ESRD-QIP.pdf. Table 13 summarizes these results, presenting changes in measure scores observed after applying the proposed small facility adjuster, as compared to measure scores calculated with the existing small facility adjuster. For the purposes of this analysis and for all of the measures, *L* was set to 11 and *C* was set to 26.

TABLE 13—IMPACT OF PROPOSED SMALL FACILITY ADJUSTER ON INDIVIDUAL MEASURE SCORES, USING THE FINAL DATASET FOR THE PY 2015 ESRD QIP

Measure	# facilities received SFA in PY 2015	National mean in the performance period (CY 2013)	# facilities receiving SFA under new method	# facilities with score change due to new SFA method N (% out of scored facilities)	# facilities with higher score under new SFA method	# facilities with lower score under new SFA method
Hgb > 12	1,253	0.4%	63	32 out of 5,513 (0.6)	32	0
Fistula	938	64.1%	391	341 out of 5,547 (6.1)	66	275
Catheter	826	11.7%	352	301 out of 5,562 (5.4)	65	236
HD Kt/V	588	91.1%	173	248 out of 5,641 (4.4)	22	226
Ped HD Kt/V	11	80.1%	1	8 out of 11 (72.7)	0	8
PD Kt/V	787	76.4%	192	400 out of 1,203 (33.3)	62	338
TPS				513 out of 5,650 (9.1)	96	417
Reduction				43 out of 5,650 (0.8)	23	20

As the results in Table 13 indicate, fewer facilities received an adjustment under the proposed small facility adjuster methodology, because small facilities with performance rates above the national mean do not receive an adjustment. However, those facilities that did receive an adjustment generally received a larger adjustment under the proposed methodology. For example, of the 43 facilities that received a different payment reduction under the proposed small facility adjuster, 23 (53 percent) received a lower payment reduction.

We also assessed the impact of the proposed small facility adjuster on the distribution of payment reductions, using the final dataset used to calculate PY 2015 ESRD QIP payment reductions. The full results of this analysis can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Small-Facility-Adjustment-Proposal-for-the-ESRD-QIP.pdf.* Table 14 below compares the distribution of payment reductions using the existing small facility adjuster to the distribution of payment reductions using the proposed small facility adjuster. For the purposes of this analysis and for all of the measures, *L* was set to 11 and *C* was set to 26.

TABLE 14—COMPARISON OF THE DISTRIBUTION OF PAYMENT REDUCTIONS DETERMINED WITH THE EXISTING AND PROPOSED SMALL FACILITY ADJUSTER, USING THE FINAL DATASET FOR THE PY 2015 ESRD QIP

Payment reduction distribution in PY 2015 using the existing SFA			Estimated payment reduction distribution in PY 2015 using the new SFA		
Payment reduction	Number of facilities	Percent of facilities	Payment reduction	Number of facilities	Percent of facilities
0.0	5,307	93.93	0.0	5,296	93.73
0.5	242	4.28	0.5	255	4.51
1.0	41	0.73	1.0	45	0.80
1.5	23	0.41	1.5	26	0.46
2.0	378	0.65	2.0	28	0.50

Note: This table excludes 488 facilities that did not receive a score because they did not have enough data to receive a TPS.

These results suggest that a similar number of facilities would receive a payment reduction under the proposed small facility adjuster methodology. A total of 343 (6.1 percent) facilities would receive a payment reduction with the existing small facility adjuster; under the proposed small facility adjuster methodology, a total of 354 (6.3 percent) facilities would have received a payment reduction. Based on the results of these analyses, we believe that the proposed small facility adjuster does not systematically alter the distribution of measure scores, TPSs, and payment reductions, as compared to the existing small facility adjuster. Coupled with the benefits of removing the within-facility standard error variable from the existing adjuster (discussed above), this leads us to believe that the benefits of the proposed adjuster outweigh the benefits of the existing adjuster. We therefore proposed to modify the methodology for determining the small facility adjustment as explained above.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Several commenters supported the overall objectives of the proposed small facility adjuster modification, but expressed concern with the proposed methodology and its alignment with the intended purpose of the SFA. These commenters were primarily concerned that too few facilities would receive an adjustment under the proposed SFA and recommended that CMS consider an SFA formula that more closely approximates the current SFA's effect on measure scores. One commenter asserted that because small facilities with performance rates above the national mean will not receive an adjustment under the proposed small facility adjuster calculation, they will experience the SFA as a performance reduction, when compared to the current SFA, which goes against the goals of the SFA generally.

Another commenter conducted a detailed analysis of the proposed SFA

using data from Dialysis Facility Compare and found that, of the 3,598 facilities in DFC, 480 met the following two criteria: (1) A facility sample size between 11 and 25, and (2) their un-adjusted performance rate was above the national median, for at least one measure. Additionally, this commenter found that 266 facilities met these criteria for at least two measures, meaning they would have received an adjustment under the current SFA but would no longer receive one under the proposed SFA. This commenter also analyzed the average magnitude that the proposed SFA would have on facilities' scores and found that for the fistula measure, for example, the current SFA adjusts performance up by an average of 2.9 percent for small facilities, whereas the proposed SFA increases performance only by an average of 1.1 percent. The commenter found similar results for other measures, and therefore urged CMS to adopt an SFA formula which more closely approximates the current SFA's impact on measure scores.

One commenter offered an alternative to the proposed Small Facility Adjuster, which was also supported by several other commenters who reviewed the alternative calculation. This alternative Small Facility Adjuster is expressed as follows:

- For the i*th* facility, suppose the facility's original measure rate is p_i and the number of patients (or other unit used to establish data minimums for the measure; for example, index discharges for the Standardized Readmission Ratio clinical measure) at the i*th* facility is n_i.
- Where the number of eligible patients (or other appropriate unit) needed to receive a score on a measure is *L* and the upper threshold for applying the small facility adjuster is *C,* the i*th* facility will be eligible for the adjustment when $L \leq n_i < C$. Accordingly, *L* and *C* set the upper and lower thresholds of eligible patients (or other appropriate unit) a facility needs to have in order to be considered for a small facility adjustment; consistent with previously finalized policies, facilities with fewer than *L* eligible patients (or other appropriate unit) for a measure will not receive a score on that measure, and facilities with more than *C* eligible patients (or other appropriate unit) for a measure will not receive an adjustment for that measure.
- Assuming $L \leq n_i < C$, let $w_i = \frac{n_i}{C}$, where n_i is the number of patients (or other appropriate unit) at the i^{th} facility and *C* is the upper thresholds of eligible patients (or other appropriate unit) a facility needs to have in order to be considered for a small facility adjustment. This calculation will produce the facility's weighting coefficient for a given clinical measure, w_i, which provides a metric for assessing the uncertainty due to small facility sizes.
- For measures where higher scores are better (for example, the Vascular Access Type (VAT): Fistula clinical measure and the Dialysis Adequacy clinical measures), a small facility's adjusted performance rates (t_i) will be pegged to the benchmark, or 90th percentile of national facility performance on a measure ($\overline{B}$) as follows:
  - If $p_i < \overline{B}$, then $t_i = w_i * p_i + (1 - w_i * \overline{B}$,
  - If p_i is greater than or equal to , the facility will not receive an adjustment.
- For measures where lower scores are better (for example, VAT: Catheter, NHSN BSI, Hypercalcemia, Standardized Readmission Ratio (SRR), and Standardized Transfusion Ratio (STrR) clinical measures), a small facility's adjusted performance rates (t_i) will be pegged to the benchmark, or 90th percentile of national facility performance on a measure ($\overline{B}$) as follows:
  - If $p_i > \overline{B}$, then $t_i = w_i * p_i + (1 - w_i * \overline{B}$
  - If p_i is less than or equal to $\overline{B}$, then the facility will not receive an adjustment
- For the standardized ratio measures, such as the SRR and STrR clinical measures, the national mean measure rate (that is, $\overline{B}$) is set to 1.

As with the proposed SFA, the alternative SFA formula suggested by the commenter does not assume a bell-shaped distribution, nor does it require the calculation of a pooled within-facility standard error. The commenter asserted that only difference between its alternative SFA calculation and the proposed SFA is that the proposed SFA uses the 50th percentile of national facility performance, whereas the commenter's alternative SFA uses the 90th percentile (that is, the benchmark) of national facility performance, to determine which small facilities should receive an adjustment. The commenter argued that using the 90th percentile of facility performance to determine which facilities will receive an adjustment provides some positive adjustment for all small facilities which may have been adversely affected by one or two challenging patients. The adjustment would be larger for worse performers and for smaller facilities and the magnitude of the adjustment under this alternative SFA would be similar to that of the current SFA.

Response: We agree that the alternative SFA suggested by a commenter and the proposed SFA accomplish very similar goals using virtually identical methodologies. Like the proposed SFA, the alternative SFA does not assume a bell-shaped distribution, nor does it require the calculation of pooled within-facility standard errors required in the current SFA. We therefore believe that, like the proposed SFA, facilities should be able to replicate this alternative SFA formula more easily than the current SFA, which requires the calculation of pooled within-facility standard errors. We also agree that the alternative SFA provides some positive adjustment for a greater number of small facilities that may be adversely affected by a small number of outlier patients than the proposed SFA,

as well as provides a greater adjustment for smaller facilities and those who appear to be ''worse'' performers based on their measure scores. We believe this particular aspect of the alternative SFA—that it provides adjustments across the range of facility performance, as opposed to only adjusting the scores of below-average performers—addresses the primary concern raised by commenters that the application of the proposed SFA did not have the same magnitude of impact on facility scores as the current SFA.

For these reasons, we are finalizing the SFA suggested by a commenter and described above for PY 2017 and future payment years of the ESRD QIP. Specifically, we are adopting the 90th percentile of facility performance as the measure score threshold for facility eligibility for the small facility adjuster instead of the proposed 50th percentile of facility performance. Under this methodology, facilities treating between 11 and 25 patients and scoring below the benchmark (that is, the 90th percentile of national facility performance) for a measure will receive an adjustment to their measure scores using the calculation provided above.

Comment: One commenter requested that CMS conduct a new analysis of the proposed small facility adjuster as applied to the proposed combined dialysis adequacy measure as the analysis provided in the proposed rule is based on the individual dialysis adequacy measures previously used in the QIP.

Response: We have conducted the analysis as requested, but have substituted the alternative small facility adjuster described above, which we are adopting for PY 2017 and future payment years, for the small facility adjuster proposed in the CY 2016 ESRD PPS proposed rule. The results of this analysis are available below using data from CY 2014.

Table 15 demonstrates the impact of the small facility adjuster we are finalizing on the PY 2018 ESRD QIP measure set, which includes all four dialysis adequacy measures, and Table 16 demonstrates the impact of the small facility adjuster on the measure set with the single comprehensive Dialysis Adequacy measure.

TABLE 15—ESTIMATED NUMBER OF FACILITIES RECEIVING A PAYMENT REDUCTION FOR PY 2018 BASED ON THE SMALL FACILITY ADJUSTER BEING FINALIZED (PY 17 THROUGH 19 SFA)

Reduction (%)	Estimated number of facilities receiving a reduction	(%) of facilities receiving a reduction
0	4889	80.98
0.5	817	13.53
1.0	263	4.36
1.5	57	0.94
2.0	11	0.18

Note: This table excludes 296 facilities that did not receive a score because they did not have enough data to receive a TPS.

TABLE 16—ESTIMATED NUMBER OF FACILITIES RECEIVING A PAYMENT REDUCTION SCALE FOR PY 2019 BASED ON THE ALTERNATIVE SMALL FACILITY ADJUSTER (PY 17 THROUGH 19 SFA)

Reduction (%)	Estimated number of facilities receiving a reduction	(%) of facilities receiving a reduction
0	4618	76.38
0.5	976	16.14
1.0	366	6.05
1.5	69	1.14
2.0	17	0.28

Note: This table excludes 287 facilities that did not receive a score because they did not have enough data to receive a TPS.

As demonstrated in the analyses above, using the PY 2018 measure set and the small facility adjuster suggested by a commenter on the PY 2018 measure set, approximately 18.1 percent of facilities would receive a reduction. By contrast, under the PY 2019 measure set and using this small facility adjuster, approximately 23.62 percent of facilities would receive a payment reduction. While this analysis reflects a small increase in the number of facilities receiving a reduction between PY 2018 and PY 2019, we believe this increase is likely the result of more facilities being eligible to receive a score on the single comprehensive Dialysis Adequacy clinical measure than on the four individual dialysis adequacy measures, as well as a decrease in the number of facilities qualifying for an adjustment on this measure for PY 2019.

Comment: One commenter expressed concerns that the proposed SFA is less transparent than the current small facility adjuster. The commenter stated that the complicated formula makes it difficult to tell if the adjuster is achieving its desired outcome and may prove difficult for small facilities to replicate without additional resources. The commenter stated that it is difficult to determine whether small facilities are receiving lower scores because of their low patient volume, as opposed to their quality of care. The commenter stated that the SFA formula should be easy to use and its impact on small facilities should be easy to replicate and understand.

Response: We believe that the proposed SFA is more transparent than the current SFA, because facilities are able to calculate the proposed SFA using data available to the facility, which facilities cannot do for the current SFA. However, as explained above, we are finalizing an alternative SFA suggested by a commenter, which we also believe will be easier to replicate than the current SFA.

Comment: One commenter expressed concerns that a smaller percentage adjustment was applied to facilities for PY 2016 than the commenter believed was going to be applied based on the example calculation provided in the CY 2014 ESRD PPS final rule with comment period.

Response: The SFA calculation for PY 2016 was implemented as finalized, and although the actual size of the adjustments was different than the estimated size of the adjustments that we set forth in the CY 2014 ESRD final rule with comment period, the estimates in that final rule were intended to be for illustrative purposes only.

For these reasons, we are finalizing the alternative SFA suggested by a commenter and described above, under which facilities treating between 11 and 25 patients and scoring below the benchmark for a clinical measure (that is, the 90th percentile of national facility performance) will receive an adjustment to their measure scores using the calculation provided above.

2. Reinstating Qualifying Patient Attestations for the ICH CAHPS Clinical Measure

In the CY 2015 ESRD PPS final rule, we finalized our proposal to remove the case minimum attestation for the ICH CAHPS reporting measure due to facility confusion regarding the attestation process (79 FR 66185). We further finalized that we would determine facility eligibility for the ICH CAHPS reporting measure based on available data submitted via CROWNWeb, Medicare claims, and other CMS administrative data sources. Following the publication of that rule we have determined that we do not have

reliable data sources for determining some of the patient-level exclusions. For example, we have been unable to locate a reliable data source for determining whether a patient is receiving hospice care or is residing in an institution such as a prison or a jail.

Although some facilities may be experiencing issues related to the attestation process (for example, during the preview period, we have encountered numerous instances where facilities have either attested inappropriately or have failed to attest in a timely fashion), we believe that facilities are generally able to determine whether their patients meet one or more of the exclusion criteria for the measure. For this reason, we believe that having facilities attest that they are ineligible for the measure will result in more accurate measure scores, as compared to using unreliable data sources to determine whether facilities treated the requisite number of eligible patients during the eligibility period, (defined as the calendar year immediately preceding the performance period). Because we have no reason to believe that reliable data sources for some of the patient-level exclusions for the ICH CAHPS clinical measure will become available in the near term, and because the PY 2017 ICH CAHPS reporting measure and the PY 2018 ICH CAHPS clinical measure employ the same exclusion criteria, we proposed to reinstate the attestation process we previously adopted in the CY 2014 ESRD PPS final rule (78 FR 72220 through 72222) beginning with the PY 2017 program year. However, we are now proposing to have facilities attest on the basis of the eligibility criteria finalized in the CY 2015 ESRD PPS final rule (79 FR 66169 through 66170). Accordingly, facilities seeking to avoid scoring on the ICH CAHPS measure due to ineligibility must attest in CROWNWeb by January 31 of the year immediately following the performance period (for example, January 31, 2017, for the PY 2018 ESRD QIP) that they did not treat enough eligible patients during the eligibility period to receive a score on the ICH CAHPS measure. Facilities that submit attestations regarding the number of eligible patients treated at the facility during the eligibility period by the applicable deadline will not receive a score on the ICH CAHPS clinical measure for that program year. Facilities that do not submit such attestations will be eligible to receive a score on the measure. However, even if a facility is eligible to receive a score on the measure because it has treated at least 30 survey-eligible patients during the eligibility period (defined as the calendar year before the performance period), the facility will still not receive a score on the measure if it cannot collect at least 30 survey completes during the performance period. Facility attestations are limited to the number of eligible patients treated at the facility during the eligibility period, and are not intended to capture the number of completed surveys at a facility during the performance period. The ESRD QIP system will determine how many completed surveys a facility received during the performance period. We are not proposing to change any of the other data minimum requirements for the PY 2017 ICH CAHPS reporting measure, or for the ICH CAHPS clinical measure in PY 2018 and future payment years. To reduce confusion, we will release a CROWN Memo detailing how facilities are expected to attest.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Many commenters supported the proposal to reinstate qualifying patient attestations for the ICH CAHPS measure. One commenter additionally recommended that CMS establish a process for facilities to confirm that the attestation has been received and that CMS delay the measure's conversion to a clinical measure until the appropriate facility exclusion data is available.

Response: We thank commenters for their support. We agree that it would be ideal if facilities could confirm that their attestation has been received, and we will consider the feasibility of implementing such a process in the future.

Comment: One commenter did not support CMS' proposal to reinstate the qualifying patient attestations for the ICH CAHPS measure because the process is challenging for smaller facilities to understand. The commenter recommended that CMS adopt ICH CAHPS patient attestations forms similar to the Home Health Care CAHPS Survey Participant Exemption Request form.

Response: The reinstated attestation for the ICH CAHPS measure is unchanged from that previously adopted in the CY 2014 ESRD PPS final rule with comment period (78 FR 72220 through 72222); we therefore believe that facilities have had sufficient experience with the attestation process and exclusion criteria to justify reinstating the attestation in order to ensure more accurate measure scores for facilities. In order to ease any residual confusion regarding the reinstated ICH CAHPS qualifying patient attestation, we will release a CROWN Memo detailing how facilities are expected to attest and the exclusion criteria for the ICH CAHPS measure prior to the attestation deadline for PY 2017. For future years of the ESRD QIP, we will consider the feasibility of adopting ICH CAHPS patient exemption request form similar to the Home Health Care CAHPS Survey Participant Exemption Request form.

For the reasons discussed above, we are finalizing our proposal to reinstate the qualifying patient attestations for the ICH CAHPS measure beginning with the PY 2017 ESRD QIP.

G. Requirements for the PY 2018 ESRD QIP

1. Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Finalized for the PY 2018 ESRD QIP

In the CY 2015 ESRD PPS final rule, we stated that we would publish values for the PY 2018 clinical measures, using data from CY 2014 and the first portion of CY 2015, in the CY 2016 ESRD PPS final rule (79 FR 66209). Upon publication of the CY 2016 ESRD PPS proposed rule, we did not have the necessary data to assign numerical values to the proposed performance standards, achievement thresholds, and benchmarks for the clinical measures, because we did not yet have complete data from CY 2014. Since that time, we have collected the data needed to calculate finalized performance standards for the PY 2018 ESRD QIP. For all of the clinical measures, including the SRR clinical measure, this data comes from the period of January through December 2014. Table 17 lists the finalized numerical values for all of the finalized PY 2018 ESRD QIP clinical measures except the ICH CAHPS clinical measure.

TABLE 17—ESTIMATED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2018 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement threshold	Benchmark	Performance standard
Vascular Access Type:			
%Fistula	53.51%	79.60%	65.94%.
%Catheter	16.79%	2.59%	8.80%.
Kt/V:			
Adult Hemodialysis	91.08%	99.35%	96.89%.
Adult Peritoneal Dialysis	75.42%	97.06%	89.47%.
Pediatric Hemodialysis	84.16%	99.06%	94.44%.
Pediatric Peritoneal Dialysis	43.22%	88.39%	72.60%.
Hypercalcemia	3.92%	0.00%	1.19%
NHSN Bloodstream Infection SIR	1.812	0	0.861
Standardized Readmission Ratio	0.996	0.555	0.996
Standardized Transfusion Ratio	1.470	0.431	0.923
ICH CAHPS	50th percentile of eligible facilities' performance during CY 2015.	15th percentile of eligible facilities' performance during CY 2015.	90th percentile of eligible facilities' performance during CY 2015.

We believe that the ESRD QIP should not have lower performance standards than in previous years. Accordingly, if the final numerical value for a performance standard, achievement threshold, and/or benchmark is worse than it was for that measure in the PY 2017 ESRD QIP, then we proposed to substitute the PY 2017 performance standard, achievement threshold, and/or benchmark for that measure.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: One commenter supported the estimated performance standard, achievement threshold, and benchmark for the ICH CAHPS clinical measure for the PY 2018 ESRD QIP.

Response: We thank the commenter for its support.

Comment: Several commenters supported CMS's proposal, for PY 2018, to set the Performance Standard, Achievement Threshold and Benchmark at the 50th, 15th, and 90th percentiles respectively, for the Clinical Measures finalized for the PY 2018 ESRD QIP, particularly where those values are higher than the current PY 2017 values.

Response: We thank the commenters for their support. For this reason, we will finalize our proposal to utilize performance standards from the previous year if they are higher than those of the next year. Accordingly, we are substituting the PY 2017 performance standards, achievement thresholds, and benchmarks for the Adult Hemodialysis Adequacy, Pediatric Hemodialysis Adequacy, and SRR clinical measures for the PY 2018 values for these measures.

Comment: One commenter expressed support for CMS's policy to maintain a previous year's benchmark if it is worse than it was for the measure in the previous year, but suggested that if data shows that performance is not as strong for a particular measure, then there may be an issue with the measure itself. The commenter recommended that rather than using prior benchmark data, CMS should consider the root cause of why performance isn't improving for those measures.

Response: We continue to believe that using prior benchmark data helps drive quality improvement for facilities and encourages them to conduct their own quality improvement initiatives. When we encounter measures with data showing that performance is consistently poor or otherwise failing to improve meaningfully over time, we look into the root cause and the reasons performance is not improving. We have done this for the measures currently included in the QIP and, where appropriate, are using prior benchmarks. In addition, we have analyzed the performance gaps between CY 2013 and CY 2014 for measures where we are substituting the PY 2017 performance standards, and have not identified any underlying issues with those measures. We will continue to monitor measure performance data in future years of the program.

Comment: One commenter requested that CMS reevaluate the PY 2018 performance standards for the NHSN BSI, SRR, and STrR clinical measures because their estimated values are all below 1.0, meaning facility performance falling within the range of expected events may generate lower QIP scores. The commenter expressed concern that this scoring issue could misrepresent performance by facilities on these measures. Another commenter did not support the estimated performance standards for the SRR or STrR clinical measures because they seem unattainable given facilities' experience with the NHSN BSI clinical measure.

Response: We thank the commenters for their comments. We note, however, that the curve for the NHSN BSI clinical measure as seen in the PY 2016 ESRD QIP is skewed due to an additional policy impacting this measure, under which facilities that fail to report a full 12 months of data for the measure automatically receive a score of zero on the measure. We have not implemented a corresponding policy for the SRR or STrR clinical measures; therefore, we have no reason to believe scores on these measures will be impacted in this way. In addition, the performance standards for the PY 2018 ESRD QIP are only used to determine the minimum TPS for a given year of the ESRD QIP. The median performance rates for the SRR, STrR, and NHSN BSI clinical measures were determined to be 0.998, 0.923, and 0.862 for SRR, STrR, respectively, for the PY 2018 ESRD QIP. The minimum TPS was determined to be the same when these values were set to 1.0. Therefore, use of the calculated median rather than 1.0 has no impact on facility-level QIP scores.

We further disagree that the estimated performance standards for the SRR or STrR clinical measures are unattainable. First, we note that the performance standards for these measures are set at the 50th percentile of facility performance, meaning that 50 percent of facilities achieve or surpass this standard. These measures are standardized ratios of performance, evaluating facilities' actual performance against their expected performance. Therefore, each facility's score on these measures will be reflective of the facility's particular patient mix and other adjustments. In addition, the achievement threshold, benchmark and performance standard for those measures are determined using the same standards as those for all of the other

clinical measure, which are intended to incentivize quality improvements while also accounting for individual facilities' past performance on the measure. We therefore believe it is appropriate to maintain uniform performance standard, achievement threshold, and benchmark policies across the ESRD QIP clinical measures.

Comment: One commenter recommended that CMS avoid implementing measures without numerical values for performance standards because it creates a moving target for quality improvement. Specifically, the commenter expressed concern about the proposed performance standard, achievement threshold, and benchmark for the PY 2018 ICH CAHPS clinical measure because performance data is not available to estimate a numerical value for these elements, and recommended that CMS revert the ICH CAHPS measure to a reporting measure. The commenter asserted that numerical performance standards inform facility decision-making in how to address patient concerns and improve patient experience ratings.

Response: We thank commenter for its recommendation and note that, in general, we seek to avoid implementing measures without numerical values for their performance standard, achievement threshold, and benchmark. In the CY 2016 ESRD PPS proposed rule, we used the most recently available data and provided numerical values for all clinical measures except the ICH CAHPS clinical measure (80 FR 37842). For the ICH CAHPS clinical measure, CY 2015 is the first year for which we will have data. Accordingly, we will propose numerical values for the performance standard, achievement threshold, and benchmark once we have collected the data for CY 2015 and conducted the necessary analyses.

Comment: One commenter recommended that CMS maintain consistency in the ESRD QIP performance period and performance standard methodology, and encouraged CMS to finalize performance periods and standards in a timely manner.

Response: We agree that maintaining consistency in the ESRD QIP performance periods and performance standards is important because it simplifies the administrative burden associated with participating in the ESRD QIP and aids facilities in understanding the requirements of the program. We note that the performance period for the majority of measures in the ESRD QIP aligns with the calendar year, and only deviates in the case of the NHSN HCP Influenza Vaccination reporting measure, for which the performance period generally aligns with the influenza season. Additionally, we appreciate that facilities want to learn as soon as possible what the ESRD QIP measure set and performance standards will be for a given year of the program. Numerical performance standards for the ESRD QIP measure set are calculated using the most recent data available for those measures in advance of the applicable performance period. We understand that this process results in facilities only receiving the finalized numerical performance standards two months before the beginning performance period; however, we believe this process is necessary in order to ensure that we set accurate performance standards for use in scoring facility performance on the ESRD QIP measure set for a given year.

For the reasons discussed above, for PY 2018, we are finalizing that we will use the performance standards in Table 17 above.

2. Modification to Scoring Facility Performance on the Pain Assessment and Follow-Up Reporting Measure

In the CY 2015 ESRD PPS final rule, we finalized the following calculation for scoring facility performance on the Pain Assessment and Follow-Up reporting measure under the PY 2018 ESRD QIP (79 FR 66211):

$$\left[\frac{\text{Number of patients for whom facility reports one of six conditions during the first six months}}{\text{Number of eligible patients in the first six months}} + \frac{\text{Number of patients for whom facility reports one of six conditions during the second six months}}{\text{Number of eligible patients in the second six months}}\right] \div 2$$

We have since determined that this calculation may unduly penalize facilities that treat no eligible patients in one of the two six-month periods evaluated under this measure; under this calculation, those facilities would have a ''0'' for the applicable period's data, in effect giving the facility half of its score on the remaining 6-month period as a measure score. In order to avoid such an undue impact on facility scores, we proposed that, beginning with the PY 2018 ESRD QIP, if a facility treats no eligible patients in one of the two 6-month periods, then that facility's score will be based solely on the percentage of eligible patients treated in the other six-month period for whom the facility reports one of six conditions.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Several commenters supported the proposal to modify the Pain Assessment and Follow-Up reporting measure scoring methodology.

Response: We thank the commenters for their support.

Comment: Some commenters requested additional clarification regarding the reasons for the proposed modification to scoring facility performance on the Pain Assessment and Follow-Up reporting measure as well as information about how the modifications will be operationalized.

Response: Under the previously finalized calculation for scoring facility performance on the Pain Assessment and Follow-Up reporting measure, facilities may have been unduly penalized for treating no eligible patients during one of the two 6-month periods that together make-up the performance period. The proposed modification is an alteration to the scoring methodology for the Pain Assessment and Follow-Up reporting measure, and therefore does not impact facilities' requirements under the measure.

For example, if a facility had zero eligible patients in the first 6-month period, then treated eligible patients in the second 6 months, the facility would automatically receive no greater than 5 points for the measure. We did not fully anticipate that such a scenario could arise, and it is one which we wish to avoid. Therefore, under the proposed calculation modification, facilities that only treat eligible patients in one of two the 6-month periods will be scored only on the percentage of eligible patients treated during that 6-month period.

Comment: One commenter requested clarification from CMS regarding the proposed modification to the Pain Assessment and Follow-Up reporting measure because it is unclear how the six-month periods relate to the measure attestations. The commenter further

recommended implementing the same proposed modification for the Screening for Clinical Depression and Follow-Up reporting measure.

Response: In order to comply with the requirements of the Pain Assessment & Follow-Up Measure, facilities must report one of six conditions in CROWNWeb once every six months per performance period for every qualifying patient, meaning that facilities will provide two separate rounds of attestations for this measure. Conditions covering the first six months of the performance period must be reported in CROWNWeb before August 1 of the performance period, and conditions covering the second 6 months of the performance period must be reported in CROWNWeb before February 1 of the year directly following the performance period (79 FR 66203 through 66204).

We did not propose to implement a corresponding modification for the Screening for Clinical Depression and Follow-Up reporting measure because facilities are only required to report one of the six conditions listed in CROWNWeb once per performance period (that is, once per calendar year) under this measure (79 FR 66200). Because reporting for the Screening for Clinical Depression and Follow-Up reporting measure occurs once per performance period, and not twice for the performance period (once every 6 months), there will not be instances where a facility is eligible for scoring based on one part of the performance period but not the other. Therefore, there is no need to change the scoring methodology for the Screening for Clinical Depression and Follow-Up reporting measure.

For the reasons discussed above, we are finalizing as proposed the modified methodology for scoring facility performance on the Pain Assessment and Follow-Up reporting measure beginning with the PY 2018 ESRD QIP.

3. Payment Reductions for the PY 2018 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the ESRD QIP scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. In the CY 2015 ESRD PPS final rule, we finalized our proposal for calculating the minimum TPS for PY 2018 and future payment years (79 FR 66221 through 66222). Under our current policy, a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if: (i) It performs at the performance standard for each clinical measure; and (ii) it receives the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2016 reporting measures (79 FR 66221). We proposed to clarify how we will account for measures in the minimum TPS when we lack the baseline data necessary to calculate a numerical performance standard before the beginning of the performance period (per criterion (i) above), because we inadvertently omitted this detail in the CY 2015 ESRD PPS final rule. Specifically, we propose, for the PY 2018 ESRD QIP, to add the following criterion previously adopted for the PY 2017 program (79 FR 66187): ''it received zero points for each clinical measure that does not have a numerical value for the performance standard established through rulemaking before the beginning of the PY 2018 performance period.'' Under this proposal, for PY 2018, a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if: (i) It performs at the performance standard for each clinical measure; (ii) it received zero points for each clinical measure that does not have a numerical value for the performance standard established through rulemaking before the beginning of the PY 2018 performance period; and (iii) it receives the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2016 reporting measures.

We were unable to calculate a minimum TPS for PY 2018 in the CY 2015 ESRD PPS final rule because we were not yet able to calculate the performance standards for each of the clinical measures. We therefore stated that we would publish the minimum TPS for the PY 2018 ESRD QIP in the CY 2016 ESRD PPS final rule (79 FR 66222).

Based on the estimated performance standards listed above, we estimated that a facility must meet or exceed a minimum TPS of 39 for PY 2018. For all of the clinical measures except the SRR, STrR, and ICH CAHPS clinical measures, these data come from CY 2014. The data for the SRR and STrR clinical measures come from CY 2013 Medicare claims. For the ICH CAHPS clinical measure, we set the performance standard to zero for the purposes of determining this minimum TPS, because we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the PY 2018 performance period. We proposed that a facility failing to meet the minimum TPS, as established in the CY 2016 ESRD PPS final rule, will receive a payment reduction based on the estimated TPS ranges indicated in Table 18 below.

TABLE 18—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2018 BASED ON DATA AVAILABLE AT PUBLICATION OF THE PROPOSED RULE

Total performance score	Reduction (%)
100—39	0.0
38—29	0.5
28—19	1.0
18—9	1.5
8—0	2.0

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: Several commenters supported CMS' proposal to continue, for PY 2018, the same policy used in PY 2017 for determining payment reductions, including the process for setting the minimum TPS. One commenter urged CMS to maintain consistency in its payment reduction methodology for future years of the ESRD QIP, because this would allow beneficiaries to better compare facility performance over time.

Response: We thank the commenters for their support.

Comment: One commenter expressed concern about the estimated minimum TPS for PY 2018, and requested that CMS provide clarification on how the mTPS was calculated. Specifically, commenter is concerned that we proposed to lower the minimum TPS for PY 2018 from 60 (the mTPS for PY 2017) to 39. The commenter stated that this proposal was confusing in light of CMS's request for comments on potentially raising the performance threshold to the 25th percentile.

Response: We have recalculated the minimum TPS for PY 2018 for all measures using updated data, including data for the NHSN BSI clinical measure, which we lacked at the time of the proposed rule's publication. Using this data, we have determined that the updated minimum TPS for PY 2018 is 49. Facilities failing to meet this minimum TPS will receive a payment reduction based on the updated TPS ranges indicated in Table 19, below.

TABLE 19—PAYMENT REDUCTION SCALE FOR PY 2018 BASED ON THE MOST RECENTLY AVAILABLE DATA FROM CY 2014

Total performance score	Reduction (%)
100–49	0.0
48–39	0.5
38–29	1.0
28–19	1.5
18–0	2.0

We have also provided two sets of tables below detailing how the minimum TPS was calculated for the PY 2018 ESRD QIP. Table 20 provides the measure score calculations used for the updated minimum TPS. Table 21 provides the total performance score calculations used to determine the minimum TPS in the proposed rule.

TABLE 20—MINIMUM TPS MEASURE SCORE CALCULATION FOR PY 2018 USING MOST RECENTLY AVAILABLE DATA

Measure	Median score for measure topics	Measure weight (%)	Measure topic weight score (= median score * measure weight)
CLINICAL MEASURES			
Clinical Care Subdomain	.....	50	.....
Kt/V (4 combined measures)	6	18	1.08
VAT (2 combined measures)	6	18	1.08
Hypercalcemia	7	7	0.49
STRR	5	7	0.35
Patient and Family Engagement/Care Coordination Subdomain	.....	30	.....
SRR	4	10	0.4
ICH CAHPS	0	20	0
Safety Subdomain	.....	20	.....
NHSN	5	20	1
Clinical Subtotal	.....	.....	*4.4*
REPORTING MEASURES			
Mineral Metabolism	9	20	0.18
Anemia Management	10	20	0.20
Pain	10	20	0.20
Depression	10	20	0.20
NHSN HCP	10	20	0.20
Reporting Subtotal	.....	.....	*9.8*

TABLE 21—TOTAL PERFORMANCE SCORE CALCULATION USED TO DETERMINE THE PY 2018 MINIMUM TPS

	Measure topic weight score (from previous table)	Clinical and reporting weights (percent)	Clinical and reporting subscores (= measure topic score * weight)	Final scores (= clinical and reporting subscores * 10)
Clinical Subtotal	4.4	90	3.96	39.6
Reporting Subtotal	9.75	10	0.975	9.8
TPS (Clinical + Reporting Subtotals)	.....	.....	4.96	49.4
TPS (rounded)	.....	.....	.....	*49*

We note that our minimum TPS policy is independent from the achievement threshold as used in the ESRD QIP scoring policy, and that these policies serve different the purposes in scoring facility performance in the ESRD QIP. The minimum TPS establishes the TPS a facility must achieve in order to avoid receiving a payment reduction for the applicable payment year of the ESRD QIP, and serves as the basis for the PY's payment reduction scale. The achievement threshold, on the other hand, is set at the 15th percentile of national performance and is used to score facility performance on individual clinical measures for a given year of the program. We therefore believe these separate policies provide distinct incentives for quality improvement among dialysis facilities. We are also continuing to look for ways to further incentivize quality improvement, one of which would be to increase the achievement threshold from the 15th to the 25th percentile.

Comment: One commenter urged CMS to monitor the implementation and impact of the QIP scoring model on the standardized ratio measures because they are fundamentally different than the other QIP clinical measures in terms of how they are calculated and the level of control dialysis facilities have on the results. The commenter pointed out that the QIP scoring model was originally designed for ''rates of compliance'' measures and is concerned about how these measures will influence QIP results given that the results are

reported categorically (*i.e.* ''worse/better than expected'' or ''as expected.'')

Response: We acknowledge that the standardized ratio measures differ from other ESRD QIP clinical measures. However, we lack reason to believe that the current ESRD QIP scoring methodology is insufficient or inappropriate for calculating facility performance on the ESRD QIP measures when the standardized ratio measures are included in a facility's score. In addition, we note that other value-based purchasing programs, such as the Hospital Value-Based Purchasing Program, score standardized ratio measures. We will continue to monitor the implementation and impact of these measures in future years of the ESRD QIP to determine if further modification to the ESRD QIP scoring methodology is necessary.

For the reasons discussed above, we are finalizing the revised minimum TPS policy for PY 2018 as proposed. We are also finalizing the updated mTPS and payment reduction scale for PY 2018 as discussed above.

4. Data Validation

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. We began a pilot data-validation program in CY 2013 for the ESRD QIP, and procured the services of a data-validation contractor that was tasked with validating a national sample of facilities' records as reported to CROWNWeb. For validation of CY 2014 data, our first priority was to develop a methodology for validating data submitted to CROWNWeb under the pilot data-validation program. That methodology was fully developed and adopted through the rulemaking process. For the PY 2016 ESRD QIP (78 FR 72223 through 72224), we finalized a requirement to sample approximately 10 records from 300 randomly selected facilities; these facilities had 60 days to comply once they received requests for records. We continued this pilot for the PY 2017 ESRD QIP, and proposed to continue doing so for the PY 2018 ESRD QIP. Under this continued validation study, we will sample the same number of records (approximately 10 per facility) from the same number of facilities (that is, 300) during CY 2016. If a facility is randomly selected to participate in the pilot validation study but does not provide us with the requisite medical records within 60 days of receiving a request, then we proposed to deduct 10 points from the facility's TPS. Once we have developed and adopted a methodology for validating the CROWNWeb data, we intend to consider whether payment reductions under the ESRD QIP should be based, in part, on whether a facility has met our standards for data validation.

In the CY 2015 ESRD PPS final rule, we also finalized that there will be a feasibility study for validating data reported to CDC's NHSN Dialysis Event Module for the NHSN Bloodstream Infection clinical measure. Healthcare-Acquired Infections (HAI) are relatively rare, and we finalized that the feasibility study would target records with a higher probability of including a dialysis event, because this would enrich the validation sample while reducing the burden on facilities. For PY 2018, we proposed to use the same methodology that was discussed in the CY 2015 ESRD QIP final rule (79 FR 66187). This methodology resembles the methodology we use in the Hospital Inpatient Quality Reporting Program to validate the central line-associated bloodstream infection measure, the catheter-associated urinary tract infection measure, and the surgical site infection measure (77 FR 53539 through 53553). For the PY 2018 ESRD QIP, we proposed to randomly select nine facilities to participate in the feasibility study for data reported in CY 2016. A CMS contractor will send these facilities quarterly requests for lists of candidate dialysis events (for example, all positive blood cultures drawn from its patients during the quarter, including any positive blood cultures that were collected from the facility's patients on the day of, or the day following, their admission to a hospital). Facilities will have 60 days to respond to quarterly requests for lists of positive blood cultures and other candidate events. A CMS contractor will then determine when a positive blood culture or other ''candidate dialysis event'' is appropriate for further validation. With input from CDC, the CMS contractor will utilize a methodology for identifying and requesting the candidate dialysis events other than positive blood cultures. The contractor will analyze the records of patients who had candidate events in order to determine whether the facility reported dialysis events for those patients in accordance with the NHSN Dialysis Event Protocol. If the contractor determines that additional medical records are needed from a facility to validate whether the facility accurately reported the dialysis events, then the contractor will send a request for additional information to the facility, and the facility will have 60 days from the date of the letter to respond to the request. Overall, we estimate that, on average, quarterly lists will include two positive blood cultures per facility, but we recognize these estimates may vary considerably from facility to facility. If a facility is randomly selected to participate in the feasibility study but does not provide CMS with the requisite lists of positive blood cultures or the requisite medical records within 60 days of receiving a request, then we proposed to deduct 10 points from the facility's TPS.

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: Several commenters requested that CMS conduct a more robust validation study for NHSN BSI, examining both the completeness of BSI data collection and the accuracy of the data collected. They argued that selecting such a small number of facilities to participate in the study may be inadequate to validate the data reported to the NHSN Dialysis Event Module and recommended that CMS reconsider the proposed sample size to include more facilities, ideally at least 5 percent of facilities. One commenter offered specific suggestions for increasing the size of the validation study. Specifically, the commenter recommended that CMS evaluate under-reporting, access type errors, application of the NHSN criteria, accessibility of reports of positive blood cultures from inpatient facilities to outpatient dialysis facilities, and the accuracy of manual- vs. electronically-submitted data. The commenter urged CMS to ensure that both small and large dialysis facilities, hospital-based centers and for-profit centers are included. Additionally, the commenter recommended that CMS validate data from facilities that use paper medical records and from facilities that use electronic medical records. Some commenters argued that the targeting of the validation study is too narrowly focused on patients with positive blood cultures and feel that the study should be expanded beyond those patients with positive blood cultures. They also argued that the validation study should look at instances where a facility reports no positive blood cultures, which is likely the result of intentional or accidental under-reporting. One commenter specifically recommended that CMS review the CDC-funded data validation project for dialysis events performed by the Tennessee Health Department and fund state health departments for on-site data validation and examination of vaccination rate reporting.

Response: We thank commenters for their recommendations about ways to

improve the NHSN BSI validation study. As noted in the CY 2015 ESRD PPS final rule with comment period (79 FR 66188), we believe it is important to demonstrate the study's feasibility and further develop the study's methodology before expanding the study to include more facilities. For future years of the program, we will consider increasing the size of the validation study to include a greater number of facilities. However, we currently include a wide variety of types of facilities, both small and large, hospital-based and for-profit, etc. in our study. In addition, the validation study is not currently limited to events collected in the dialysis facility, as one commenter suggested; it also includes positive blood cultures collected or identified at hospitals. We look forward to continuing to refine this study to ensure that we are collecting as much reliable and useful data about bloodstream infections as possible.

Comment: Numerous commenters did not support CMS's proposal to deduct 10 points from a facility's TPS if they are selected to participate in a data validation study and fail to provide CMS with the requested data within the allotted time because 10 points can have such a significant impact on selected facilities' TPSs and because the Conditions for Coverage already require that facilities comply with data validation requests. Several commenters expressed concerns that this 10-point deduction for non-compliance could mislead beneficiaries on the quality of care delivered by the facility and argued that there is no evidence that facilities are noncompliant with requests for this data. Commenters argued that failing to supply CMS with this data does not measure the quality of care provided by the facility. Additionally, commenters stated that facilities should not be penalized without having the opportunity to dispute the noncompliance allegations and to make any needed corrections as appropriate.

Response: We appreciate commenters' concerns about the impact of a 10-point reduction to a facility's TPS based on noncompliance with the data request. We also recognize that the ESRD Conditions for Coverage already require facilities to comply with these requests for medical records, and we are not aware of any evidence suggesting that they are not already doing so. Nevertheless, we continue to believe that assessing penalties on a facility's TPS is the surest way to ensure that facilities provide the medical records needed to complete the studies. This is because facilities are not typically surveyed for compliance with the Conditions for Coverage every year, so deducting points from a facility's TPS provides a more certain process for penalizing noncompliance with the requirements of the validation studies. As stated in the CY 2015 ESRD PPS final rule with comment period, our policy to deduct points from a facility's TPS is consistent with section 1881(h)(3)(A)(i) of the Act, because it is part of our methodology for assessing the total performance of each provider of services and renal dialysis facility based on the performance standards with respect to the measures selected (79 FR 66189). The main purpose of these studies is to assess whether facilities are reporting accurate data, and we have determined that review of medical records is integral to that determination. We will consider the feasibility of implementing a method for facilities to dispute the noncompliance allegations and to make any needed corrections for future years of the ESRD QIP.

Comment: One commenter requested that CMS publish the results of the ongoing CROWNWeb validation study as well as a timeline for the expected release of such results.

Response: We anticipate releasing the results of this study in the near future, and are aiming for publication by December 2015.

Comment: One commenter expressed concerns with the proposed 60-day compliance requirement for the NHSN BSI measure, and suggested that a 90-day period would be more appropriate.

Response: We disagree that the 60-day timeframe is too short for facilities to respond to requests to validate medical records, because facilities should have these records on hand, and sampled facilities will only be required to submit a small number of medical records for the NHSN Bloodstream Infection study.

Comment: A few commenters raised concerns that the data validation study appears to be an audit of facility data to confirm the accuracy of the data reported and that therefore it is important to ensure that there are processes in place to address disputes which may arise and to protect facilities so that they have the opportunity to appeal both at the contractor and at higher levels of review if necessary.

Response: As stated previously in the CY 2015 final rule with comment period (79 FR 66188), we agree that one of the purposes of the validation pilot is to identify instances in which facilities are reporting invalid data to CROWNWeb. However, we do not believe it is appropriate to designate the validation study as an ''audit'' of facility data, because the ultimate objective of the study is to improve the validity of data reported to CROWNWeb, rather than to penalize facilities for reporting invalid data. We further note that we did not propose to penalize facilities for reporting invalid data; if and when we propose to do so in future rulemaking, we will consider implementing an appeal process facilities can use to contest CMS determinations that invalid data was reported to CROWNWeb.

Comment: One commenter encouraged CMS to suspend the validation study and the resulting payment penalties in favor of working directly with facilities that appear to have data submission problems to help them identify workable solutions which can be remedied. In this way, accurate data submission will be encouraged rather than penalizing facilities as much for not submitting data as they would be penalized for not providing quality patient care. Another commenter argued that, given that CMS is conducting a feasibility study of a validation methodology, those facilities chosen should not be penalized with a deduction in their TPS as a result of non-compliance. The commenter recommended that the penalty be delayed until a full validation study is in place.

Response: We thank the commenter for its recommendation. However, before we can undertake a work-intensive and highly individualized remediation effort such as that described by the commenter, we must develop a more fulsome understanding of the issues impacting facility data reporting. We believe the current data validation studies are a first and critical step toward developing this understanding. In the interim, we urge facilities experiencing issues with data submission to contact the CROWNWeb and/or NHSN Help Desks for support. We also note that the current data validation studies do not penalize facilities for reporting incorrect or invalid data; the 10-point TPS reduction is keyed to non-compliance with only the submission of data needed for the studies themselves. We also disagree that the penalty for non-compliance with the feasibility study of our proposed validation methodology should be delayed until a full validation is in place. Facility compliance is essential to the success of the feasibility study, and we wish to provide a strong incentive for facilities to transmit the requested medical records needed to validate the NHSN data. Most importantly, however, this feasibility study will provide the basis for a more comprehensive validation study that we hope to begin in the near future.

Comment: One commenter expressed concerns that obtaining only positive blood culture data may not lead to comprehensive validation of data reported to NHSN and recommended that IV antimicrobial start and pus, redness or increased swelling at the vascular access site should also be considered.

Response: We will take this recommendation into consideration as we continue to refine the NHSN data validation feasibility study.

Comment: One commenter supported the quarterly collection of NHSN BSI data and stated that such a requirement is not a burdensome task for facilities, especially when the expectation is clearly articulated in advance.

Response: We agree that the quarterly collection of NHSN BSI data is not a burdensome task for facilities.

For these reasons, we are finalizing, as proposed, the continuation of the CROWNWeb pilot data validation and the feasibility study for the validating data reported to CDC's NHSN Dialysis Event Module for the NHSN Bloodstream Infection clinical measure.

H. Requirements for the PY 2019 ESRD QIP

1. Replacement of the Four Measures Currently in the Dialysis Adequacy Clinical Measure Topic Beginning With the PY 2019 Program Year

We consider a quality measure for removal or replacement if: (1) Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made (in other words, the measure is topped-out); (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative or unintended consequences (77 FR 67475). In the CY 2015 ESRD PPS final rule, we adopted statistical criteria for determining whether a clinical measure is topped out, and also adopted a policy under which we could retain an otherwise topped-out measure if we determined that its continued inclusion in the ESRD QIP measure would address the unique needs of a specific subset of the ESRD population (79 FR 66172 through 66174).

Subsequent to the publication of the CY 2015 ESRD PPS final rule, we evaluated the finalized PY 2018 ESRD QIP measures against all of these criteria. We determined that none of these measures met criterion (1), (2), (3), (5), (6), or (7). As part of this evaluation for criterion one, we performed a statistical analysis of the PY 2018 measures to determine whether any measures were ''topped out.'' The full results of this analysis can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Topped-Out-Analysis-of-ESRD-QIP-Clinical-Measures-for-PY-2018.pdf* and a summary of our topped-out analysis results appears in Table 22 below.

TABLE 22—PY 2018 CLINICAL MEASURES USING CROWNWEB AND MEDICARE CLAIMS DATA

Measure	N	75th percentile	90th percentile	Std. error	Statistically indistinguishable	Truncated CV	TCV< 0.10
Adult HD Kt/V	5,822	97.0	98.3	0.09	No	0.03	Yes.
Pediatric HD Kt/V	7	94.4	96.9	13.4	Yes	0.23	No.
Adult PD Kt/V	1,287	94.4	97.1	0.45	No	0.10	No.
Pediatric PD Kt/V	3	88.4	88.4	13.9	Yes	N/A [1]	N/A. [1]
VAT: Fistula [2]	5,763	73.3	79.7	0.15	No	0.14	No.
VAT: Catheter [3]	5,744	5.4	2.7	0.10	No	<0.01	Yes.
Hypercalcemia [2]	6,042	0.33	0.0	0.03	No	<0.01	Yes.

[1] Insufficient data.
[2] Medicare claims data from CY 2014 were used in these calculations.
[3] CROWNWeb data from CY 2014 was used in this calculation.

As the information presented in Table 22 indicates, none of these clinical measures are currently topped-out in the ESRD QIP. We note that only three facilities had 11 or more qualifying patients for the Pediatric Peritoneal Dialysis Adequacy clinical measure, resulting in insufficient data available to calculate a truncated coefficient of variation. However, because the Pediatric Peritoneal Dialysis Adequacy clinical measure addresses the unique needs of the pediatric population, we are not proposing to remove the measure at this time. Accordingly, we are not proposing to remove any of these measures from the ESRD QIP.

Beginning with the PY 2019 ESRD QIP, we proposed to replace the four measures in the Kt/V Dialysis Adequacy measure topic—(1) Hemodialysis Adequacy: Minimum delivered hemodialysis dose; (2) Peritoneal Dialysis Adequacy: Delivered dose above minimum; (3) Pediatric Hemodialysis Adequacy: Minimum spKt/V; and (4) Pediatric Peritoneal Dialysis Adequacy—with a single more broadly applicable measure for the topic. The new measure, Delivered Dose of Dialysis above Minimum—Composite Score clinical measure (''Dialysis Adequacy clinical measure'') (Measure Applications Partnership #X3717) [4], is a single comprehensive measure of dialysis adequacy assessing the percentage of all patient-months, for both pediatric and adult patients, whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified Kt/V threshold during the performance period. As discussed in more detail below, this measure's specifications allow the measure to capture a greater number of patients, particularly pediatric hemodialysis and peritoneal dialysis patients, than the four individual dialysis adequacy measures, and will result in a larger and broader collection of data from patients whose

[4] Although we correctly identified the name of the proposed measure and the specifications for that measure in the proposed rule, we inadvertently misidentified the MAP ID number as X3717. The correct MAP ID number for the proposed measure is X2051. See *https://www.qualityforum.org/map/*. The description of the measure can be found under the title ''Spreadsheet of MAP 2015 Final Recommendations.''

dialysis adequacy is assessed under the ESRD QIP. The measure assesses the adequacy of dialysis using the same thresholds applied to those patients by the existing dialysis adequacy measures, as described below. For these reasons, we believe the new dialysis adequacy measure meets criterion four above. We therefore proposed to remove the four individual measures within the Kt/V Dialysis Adequacy Measure Topic, as well as the measure topic itself, and to replace those measures with a single Dialysis Adequacy clinical measure beginning with the PY 2019 ESRD QIP. However, if based on public comments, we do not finalize our proposal to adopt the Dialysis Adequacy clinical measure, then we would not finalize this proposal to remove these measures and the Dialysis Adequacy measure topic.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Several commenters supported CMS's continued efforts to examine dialysis adequacy in the ESRD QIP as well as the proposal to remove the four separate dialysis adequacy clinical measures and replace them with a single comprehensive dialysis adequacy clinical measure because this single measure will capture a greater number of patients and make it less likely for one patient at a smaller facility to skew the facility's results on a measure.

Response: We thank the commenters for their support.

Comment: Once commenter expressed concerns about the fact that CMS removed the dialysis adequacy measure from the PQRS because it is ''topped out.'' The commenter fears that including the measure in one quality reporting program and not in another sends a mixed message. Furthermore, the commenter argued that there should be common goals among all providers, facilities and physicians alike, in order to deliver high quality patient outcomes.

Response: We acknowledge that, in the CY 2016 PFS proposed rule, CMS proposed to remove the Adult Kidney Disease: Hemodialysis Adequacy: Solute measure due to this measure representing a clinical concept that does not add clinical value to PQRS, and because eligible professionals consistently meet performance on this measure with performance rates close to 100 percent, suggesting that there is no gap in care (80 FR 41861). However, quality measures may be topped-out in one program and not in another because the goals, patient populations, and clinical concerns addressed in these programs are often quite different. While the PQRS Adult Kidney Disease measure is similar to the ESRD QIP measure, the PQRS measure is specified at the eligible professional level, assessing the care that each eligible professional is providing to his or her patients. In contrast, the ESRD QIP measure is specified for use at the facility level and therefore reflects the ESRD QIP's focus on ensuring that facilities, as a whole, provide quality care to all patients. In addition, the PQRS measure assesses only the care provided to adult hemodialysis patients, whereas the ESRD QIP measure assesses the care provided to adult and pediatric patients on either hemodialysis or peritoneal dialysis.

2. Measures for the PY 2019 ESRD QIP

We received a number of comments regarding the ESRD QIP measure set generally and the direction of future measure development and adoption for the program.

Comment: One commenter urged CMS to adopt more clinical risk-adjusted measures that capture the effective management of dialysis patients, such as the Standardized Hospitalization Ratio (SHR) or the Standardized Mortality Ratio (SMR). The commenter added that the agency previously considered, but did not adopt, the SHR measure for the PY 2014 ESRD QIP and believes that these measures should be considered for future payment years.

Response: We are continuing to develop additional appropriate clinical risk-adjusted measures to include in the ESRD QIP's measure set, and invite the ESRD community to work with us to identify such measures for future payment years.

Comment: Several commenters criticized the ESRD QIP's current measure set for several reasons: first, they believe that the measures focus predominantly on in-center hemodialysis patients without examining the unique circumstances of home hemodialysis patients; second, they would like CMS to implement more pediatric ESRD quality measures in the ESRD QIP; third, commenters would like CMS to adopt more evidence-based measures that promote the delivery of high-quality care and improved patient outcomes; and finally, commenters would like CMS to consider more patient-reported outcomes.

Some of the specific measures commenters would like to see are: (1) Measures that account for the unique circumstances of patients on home hemodialysis; (2) a reporting measure assessing whether the patient ''has a voice'' during dialysis treatment, under which a patient would be asked about their experience on dialysis immediately following each treatment (commenters stated that these conversations might help facilities to better understand the patient's concerns about his or her particular treatment and any possible need for adjustments based on patient preference); (3) a measure establishing a minimal standard for anemia management because current evidence regarding the reduction of ESA use does not evaluate whether this decline is consistent with good patient care, particularly for home hemodialysis patients who are only seen in the dialysis facility setting once per month; (4) a measure of the percent of patients at a clinic who are using a home dialysis option; (5) a Patient Informed Consent for Anemia Treatment clinical measure that includes quality of life data; (6) a measure examining the percentage of incident patients, those who are initially starting hemodialysis or peritoneal dialysis for the first time with AVF, arteriovenous graft, and PD catheters; (7) a measure examining the percentage of prevalent patients, those patients already on dialysis and who have working vascular or PD access excluding central venous catheters; (8) a measure on Cramping and Washed-Out feeling; (9) a measure on Healthy Days at home; (10) a measure on Advanced Directives in patients with ESRD. One commenter noted that the two recommended catheter measures listed above (#6 and 7) are important because catheter use continues to be very high among prevalent ESRD patients, despite the improved clinical outcomes associated with arteriovenous access, and argued that these recommended measures could decrease catheter use among ESRD patients.

Response: We thank the commenters for their recommendations, and will take these measure topics into consideration as we continue to develop the ESRD QIP measure set for future years of the program. We note that because the home hemodialysis, peritoneal dialysis and pediatric dialysis patient populations remain relatively small, establishing facility-level measures specific to these populations present substantial challenges. Specifically, there is a lack of clinical evidence available to set performance standards because there are relatively few home hemodialysis, peritoneal dialysis and pediatric dialysis patients, compared to in-center hemodialysis patients. In addition, small patient populations within individual facilities may result in measure reliability issues, which will

need to be addressed before the measure can be operationalized in the ESRD QIP.

Comment: One commenter requested that CMS develop a validated experience instrument for assessing the home dialysis population because home hemodialysis patients constitute 10 percent of the ESRD population and are currently excluded from the ICH CAHPS clinical measure, the only patient experience measure in the ESRD QIP.

Response: We appreciate the commenter's interest in ensuring that home dialysis patients are appropriately included in the ESRD QIP. While we are aware of interest in an experience of care survey, such as the Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, for home dialysis patients, we do not have immediate plans to extend the types of patients covered by our experience of care surveys in this area, due to resource constraints and questions regarding the feasibility of expanding the current survey to include home hemodialysis patients. As we continue with the initial implementation and public reporting for the In-Center Hemodialysis CAHPS Survey, we will consider ways to capture these patients in the ESRD QIP, including developing measures that would assess their quality of care.

Comment: One commenter supported the adoption of measures on bloodstream infection levels in ESRD patients, and recommended that CMS be mindful of the fact that the pediatric patient population may be disproportionately at risk for bloodstream infections.

Response: We will continue to take the unique needs and characteristics of the pediatric patient population into consideration in future measure development efforts.

Comment: One commenter suggested that CMS convene a Technical Expert Panel to develop a measure capturing patient education. The commenter further recommended that a good first step would be to compile education-related responses to the CAHPS survey (specifically questions 26, 27 and 30).

Response: We thank the commenter for the suggestion to develop a measure on patient education. We are considering a variety of measure development activities for the coming years, and will take this suggestion into consideration.

Comment: One commenter supported CMS's decision not to include hospitalizations and mortality in the ESRD QIP's measure set because of a belief that such measures are inappropriate in a pay-for-performance program while the impact of socio-demographic status on their rates is still being fully debated. Additionally, the commenter added that if these measures are adopted in future years of the QIP, facilities should be compared to peers serving similar socio-demographic populations.

Response: We appreciate the commenter's support and will consider the recommendation in the event that the SMR and SHR measures are considered for adoption in future years of the QIP.

Comment: One commenter expressed concern about the number of measures included in the QIP that are not NQF-endorsed.

Response: We agree that in general it is best for the ESRD QIP to adopt measures that are NQF-endorsed. Where it is feasible and practicable to adopt an NQF-endorsed measure, we do so. However, in instances where a measure has not been NQF-endorsed for a topic that we feel is of importance for the clinical care and outcomes of patients with ESRD, or where we feel a non-endorsed measure is superior to an NQF-endorsed measure on the same topic, we believe it is appropriate to adopt a non-endorsed measure. In proposing to adopt non-endorsed measures, we give due consideration to NQF-endorsed measures, as well as those adopted by other consensus organizations.

a. PY 2018 Measures Continuing for PY 2019 and Future Payment Years

We previously finalized 16 measures in the CY 2015 ESRD PPS final rule for the PY 2018 ESRD QIP, and these measures are summarized in Table 23 below. In accordance with our policy to continue using measures unless we propose to remove or replace them, (77 FR 67477), we stated in the proposed rule that we would continue to use 12 of these measures in the PY 2019 ESRD QIP. We also proposed to remove four clinical measures—(1) Hemodialysis Adequacy: Minimum delivered hemodialysis dose; (2) Peritoneal Dialysis Adequacy: Delivered dose above minimum; (3) Pediatric Hemodialysis Adequacy: Minimum spKt/V; and (4) Pediatric Peritoneal Dialysis Adequacy—and replace them with a single, comprehensive clinical measure covering the patient populations previously captured by these four individual clinical measures.

TABLE 23—PY 2018 ESRD QIP MEASURES BEING CONTINUED IN PY 2019

NQF #	Measure Title and Description
0257	Vascular Access Type: AV Fistula, a clinical measure. Percentage of patient-months on hemodialysis during the last hemodialysis treatment of the month using an autogenous AV fistula with two needles.
0256	Vascular Access Type: Catheter ≥ 90 days, a clinical measure. Percentage of patient-months for patients on hemodialysis during the last hemodialysis treatment of month with a catheter continuously for 90 days or longer prior to the last hemodialysis session.
N/A[1]	National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Patients, a clinical measure. Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.
1454	Hypercalcemia, a clinical measure. Proportion of patient-months with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.
2496	Standardized Readmission Ratio, a clinical measure. Standardized hospital readmissions ratio of the number of observed unplanned readmissions to the number of expected unplanned readmissions.
N/A	Standardized Transfusion Ratio, a clinical measure. Risk-adjusted standardized transfusion ratio for all adult Medicare patients.
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure. Facility administers, using a third-party CMS-approved vendor, the ICH CAHPS survey in accordance with survey specifications and submits survey results to CMS.
N/A[2]	Mineral Metabolism Reporting, a reporting measure. Number of months for which facility reports serum phosphorus or serum plasma for each Medicare patient.

TABLE 23—PY 2018 ESRD QIP MEASURES BEING CONTINUED IN PY 2019—Continued

NQF #	Measure Title and Description
N/A	Anemia Management Reporting, a reporting measure. Number of months for which facility reports ESA dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient.
N/A[3]	Pain Assessment and Follow-Up, a reporting measure. Facility reports in CROWNWeb one of six conditions for each qualifying patient once before August 1 of the performance period and once before February 1 of the year following the performance period.
N/A[4]	Clinical Depression Screening and Follow-Up, a reporting measure. Facility reports in CROWNWeb one of six conditions for each qualifying patient once before February 1 of the year following the performance period.
N/A[5]	NHSN Healthcare Personnel Influenza Vaccination, a reporting measure. Facility submits Healthcare Personnel Influenza Vaccination Summary Report to CDC's NHSN system, according to the specifications of the Healthcare Personnel Safety Component Protocol, by May 15 of the performance period.

[1] We note that this measure is based upon a current NQF-endorsed bloodstream infection measure (NQF#1460).
[2] We note that this measure is based upon a current NQF-endorsed serum phosphorus measure (NQF #0255).
[3] We note that this measure is based upon a current NQF-endorsed pain assessment and follow-up measure (NQF #0420).
[4] We note that this measure is based upon a current NQF-endorsed clinical depression screening and follow-up measure (NQF #0418).
[5] We note that this measure is based upon an NQF-endorsed HCP influenza vaccination measure (NQF #0431).

We received comments on PY 2018 Measures Continuing for PY 2019 and future years. The comments and our responses are set forth below.

Comment: A number of commenters expressed views on measures which were previously adopted in the ESRD QIP. Some commenters were supportive of previously adopted measures, and some recommended changing measure specifications for some measures. Other commenters requested that CMS consider removing previously added measures from the ESRD QIP, specifically, the NHSN BSI clinical measure, the SRR clinical measure, the STrR clinical measure, the ICH CAHPS clinical measure, the NHSN HCP Influenza Vaccination reporting measure, the Screening for Clinical Depression and Follow-Up reporting measure, and the Pain Assessment and Follow-Up reporting measure, because a number of these measures are under review at NQF, are inappropriate for facilities due to concerns about measure reliability or validity, or are too burdensome for facilities.

Response: We thank the commenters for their suggestions. At this time, we are not removing or modifying any of the measures suggested by commenters. We did not propose to remove any measures from the ESRD QIP in the CY 2016 ESRD PPS proposed rule. Further, there is no evidence that continued use of the measures as specified raises patient safety concerns that would require immediate removal of the measures based on the process finalized in the CY 2013 ESRD PPS final rule with comment period (77 FR 67475). However, we will take these suggestions into consideration in future years using the measure removal criteria we finalized in the CY 2013 ESRD PPS final rule with comment period (77 FR 67475) and further clarified in the CY 2015 ESRD PPS final rule with comment period (79 FR 66171 through 66174). We continue to believe there is value in collecting and reporting these measures at this time.

Comment: Numerous commenters requested that CMS modify the SRR clinical measure's exclusion criteria to reflect the measure as recently modified and endorsed at NQF under the All-Cause Admissions and Readmissions Measures project. Specifically, commenters requested that CMS incorporate an exclusion for patients who are readmitted to a hospital within the first one-to-three days following their hospital discharge.

Response: The SRR clinical measure was submitted for review as part of the NQF's All-Cause Admissions and Readmissions Measures project, during which the Steering Committee, NQF members, and the public discussed the appropriateness of including patients who are readmitted to a hospital within three days of discharge in the measure. In the CY 2015 ESRD PPS final rule with comment period, we expressed our initial belief that these patients should be included in the SRR measure because this three-day readmission timeframe represents an opportunity for quality improvement (79 FR 66177). However, following detailed discussions at NQF, we now believe that excluding readmissions within the first three days of discharge is critical in order to avoid holding facilities accountable for events largely beyond their control. These readmissions are likely to occur during the period when the dialysis facility may not have had an opportunity to see the patient for treatment, and, at present, facilities do not systematically receive data about their patients from the hospital when they are readmitted, thus limiting the facilities' ability to engage in quality improvement for this specific subpopulation at this time. As stated in the CY 2014 ESRD PPS final rule with comment period, we believe it is important to have in place a process which allows the ESRD QIP to incorporate non-substantive updates to a measure, in order to ensure that measures adopted for the ESRD QIP remain up-to-date and clinically relevant (77 FR 67476–67477). We believe that excluding readmissions within the first three days of discharge constitutes a non-substantive technical update to the measure; for these reasons, beginning with PY 2017, we are making this technical update to the SRR clinical measure and are adopting this exclusion. We will exclude readmissions within the first 1–3 days of an initial discharge from the SRR clinical measure. The SRR clinical measure specifications, as well as the SRR measure methodology report, are both available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html* and *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/MeasureMethodologyReportforthe ProposedSRRMeasure.pdf*, respectively.

b. Dialysis Adequacy Clinical Measure Beginning With the PY 2019 ESRD QIP

Section 1881(h)(2)(A)(i) of the Act states that the ESRD QIP measure set must include measures on ''dialysis adequacy.'' Kt/V is a widely accepted measure of dialysis adequacy in the ESRD community. It is a measure of small solute (urea) removal from the body, is relatively simple to measure and report, and is associated with survival among dialysis patients. While

the current dialysis adequacy measures have allowed us to capture a greater proportion of the ESRD population than previously accounted for under the URR Hemodialysis Adequacy clinical measure, the specifications for these measures still result in the exclusion of some patients from the measures. For example, the Pediatric Hemodialysis Adequacy clinical measure's specifications have limited the number of pediatric patients included in the ESRD QIP because very few facilities (10 facilities, based on CY 2013 data) were eligible to receive a score on the measure. We are therefore proposing to adopt a single comprehensive Dialysis Adequacy clinical measure under the authority of section 1881(h)(2)(A)(i) of the Act.

The Measure Applications Partnership conditionally supported the proposed Dialysis Adequacy clinical measure in its *2015 Pre-Rulemaking Report,* noting that this measure meets critical program objectives to include more outcome measures and measures applicable to the pediatric population in the set.[5]

The Dialysis Adequacy clinical measure assesses the percentage of all patient-months for both adult and pediatric patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the performance period. A primary difference between the single comprehensive Dialysis Adequacy clinical measure and the four previously finalized dialysis adequacy clinical measures is how facility eligibility for the measure is determined. Under the four previously finalized dialysis adequacy clinical measures, facility eligibility was determined based on the number of qualifying patients treated for each individual measure (for example, the number of qualifying adult hemodialysis patients for the Hemodialysis Adequacy: Minimum Delivered Hemodialysis Dose clinical measure). As a result, a facility had to treat at least 11 qualifying patients for each of these measures in order to receive a score on that measure. By contrast, a facility's eligibility to receive a score on the proposed Dialysis Adequacy clinical measure, which includes both adults and children, and both hemodialysis and peritoneal dialysis modalities, is determined based on the total number of qualifying patients treated at a facility. As a result, a facility that would not be eligible to receive a score on one or more of our current dialysis adequacy clinical measures because it did not meet the case minimum for one or more of those measures would be eligible to receive a score on the proposed dialysis adequacy measure if it had at least 11 total qualifying patients, defined as adults and pediatric patients receiving either hemodialysis or peritoneal dialysis. Therefore, we anticipate that adopting the single comprehensive Dialysis Adequacy clinical measure will allow us to evaluate the care provided to a greater proportion of ESRD patients, particularly pediatric ESRD patients.

We proposed that patients' dialysis adequacy would be assessed based on the following Kt/V thresholds previously assessed under the individual dialysis adequacy clinical measures:

- For hemodialysis patients, all ages: spKt/V ≥ 1.2 (calculated from the last measurement of the month)
- For pediatric (age < 18 years) peritoneal dialysis patients: Kt/V urea ≥ 1.8 (dialytic + residual, measured within the past six months)
- For adult (age ≥ 18 years) peritoneal dialysis patients: Kt/V urea ≥ 1.7 (dialytic + residual, measured within the past four months)

These thresholds reflect the best evidence-based minimum threshold for adequate dialysis for the described patient groups and are consistent with dialysis adequacy measures previously implemented in the QIP. Patient eligibility for inclusion in the measure would be determined on a patient-month level, based on the patient's age, treatment modality type, whether a patient has been on dialysis for 90 days or more, and the number of hemodialysis treatments the patient receives per week. All eligible patient-months at a facility would be counted toward the denominator. Eligible patient months where the patient met the specific dialysis adequacy threshold would be counted toward the numerator. Technical specifications for the Dialysis Adequacy clinical measure can be found at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We sought comments on our proposal to adopt this measure beginning with the PY 2019 ESRD QIP. The comments and our responses are set forth below.

Comment: A number of commenters supported the comprehensive Dialysis Adequacy clinical measure because adopting the single measure in place of the four individual measures would reduce the dilution of measure scores in the ESRD QIP and simplify the ESRD QIP measure set.

Response: We thank the commenters for their support.

Comment: One commenter expressed concerns with removing the current indicators for dialysis adequacy because of the possibility this will lead to inaccurate reporting. The commenter argued that removing the Pre/post dialysis urea nitrogen, Pre/post dialysis weight, and duration of treatment will enable the facility to report adequacy based on inaccurate blood draws, access recirculation, etc., thereby increasing the likelihood of better outcomes for the facility. Because Kt/V is a calculated outcome, the commenter urged CMS to consider having the CROWNWeb database calculate the actual Kt/V using the already available information, which could potentially eliminate the tweaking of data currently being submitted.

Response: The proposed Dialysis Adequacy clinical measure uses the same data submission requirements previously used for the four individual dialysis adequacy clinical measures, and is therefore not subject to the concerns raised. Furthermore, facilities have never been required to report pre/post dialysis urea nitrogen, pre/post dialysis weight or duration of treatment in the QIP.

Comment: One commenter urged CMS to consider patients who transfer from one modality to another to be new patients in that modality for adequacy scoring. The commenter explained that when a patient transitions from hemodialysis to peritoneal dialysis, the peritoneal dialysis scoring methodology assumes there is a peritoneal dialysis Kt/V reading within the last 4 months, without recognition that the patient has recently transitioned to this modality. The commenter argued that, as a result of this scoring methodology, dialysis facilities are forced to attempt to immediately conduct a peritoneal dialysis adequacy test, without a sufficient stabilization period in the new treatment modality.

Response: Under the single comprehensive Dialysis Adequacy clinical measure, if a patient changes from hemodialysis to peritoneal dialysis during a month, the patient would be included in both the HD and PD Kt/V measure calculations. The 2006 KDOQI Clinical Practice Guidelines for peritoneal dialysis adequacy (Guideline 2.1.2) state ''the total solute clearance (residual kidney and peritoneal, in terms of Kt/V) should be measured within the first month after initiating dialysis therapy and at least once every 4 months thereafter.'' While this measure is consistent with the

[5] *https://www.qualityforum.org/map/. This report can be found at the preceding Web site under the title ``Spreadsheet of MAP 2015 Final Recommendations.''*

guideline, we acknowledge that a patient may be included in the peritoneal dialysis Kt/V measure calculation in the same month their modality changed to peritoneal dialysis, and that peritoneal dialysis clearance is typically not measured right away or even in the same month as the peritoneal dialysis catheter insertion, as the peritoneal membrane is in a state of flux and its membrane transport characteristics are unstable for a few weeks. We therefore use the data reported in conjunction with Medicare dialysis facility claims value code D5: Result of last Kt/V reading and occurrence code 51: Date of last Kt/V reading, to determine whether the patient was on peritoneal dialysis or hemodialysis, and whether they switched modalities during the reporting month. The claims reporting instructions indicate that for peritoneal dialysis patients this should be within the last 4 months of the claim date of service. All monthly claims with valid peritoneal dialysis Kt/V values will be used in the calculation.

Comment: One commenter expressed concern that benchmarking all facilities treating any pediatric patients against those treating larger volumes of pediatric patients under the comprehensive Kt/V Dialysis Adequacy clinical measure may skew the results for ESRD facilities treating smaller numbers of pediatric ESRD patients because these facilities are less familiar with how to best manage dialysis treatments for pediatric patients.

Response: Performance on the Dialysis Adequacy clinical measure is based on the total number of qualifying patients—adult and pediatric, and hemodialysis and peritoneal dialysis modalities—treated at the facility, and the number of those patients meeting the applicable Kt/V threshold. Therefore, under this measure, facilities are assessed on the clinical care provided to all qualifying patients, and performance across facilities is based on the same holistic view of clinical care. As a result, facilities' management of a specific subgroup will not be compared directly to that of other facilities. We believe this measure therefore properly incentivizes facilities to properly manage the care of all patients, including pediatric patients, seen at the facility.

Comment: One commenter noted that when this measure was reviewed by the Measure Applications Partnership, it was characterized by CMS as a composite measure; however, the proposed measure as described appears to be a pooled measure with a different set of evaluation criteria.

Response: We acknowledge that there might have been some confusion surrounding our use of the term ''composite'' in the title of the proposed measure, especially because we are now aware that the NQF uses a specific set of criterion to determine whether a measure is a composite for endorsement purposes. However, the measure specifications presented in the CY 2016 ESRD PPS proposed rule are identical to those submitted for review by the Measure Applications Partnership, and the calculation methodology uses a pooled approach. We have developed the following table comparing the specifications of the Delivered Dose of Dialysis above Minimum—Composite Score measure submitted to the Measure Applications Partnership and the Dialysis Adequacy clinical measure, which we have renamed in full as Delivered Dose of Dialysis above Minimum.

TABLE 24—COMPARISON OF DELIVERED DOSE OF DIALYSIS ABOVE MINIMUM—COMPOSITE SCORE MEASURE AND PROPOSED DIALYSIS ADEQUACY CLINICAL MEASURE SPECIFICATIONS

Specification component	Delivered dose of dialysis above minimum—composite score [6]	Proposed dialysis adequacy clinical measure [7]
Numerator	Number of patient months in the denominator whose delivered dose of dialysis met the specified thresholds. The thresholds are as follows: • Hemodialysis (all ages): Kt/V >= 1.2. • Peritoneal dialysis (pediatric): Kt/V >= 1.8 (within past 6 months). • Peritoneal dialysis (adult): Kt/V >= 1.7 (within past 4 months).	Number of patient months in the denominator whose delivered dose of dialysis met the specified thresholds. The ranges are as follows: • Hemodialysis (all ages): Kt/V >= 1.2 (calculated from the last measurement of the month). • Peritoneal dialysis (pediatric): Kt/V >= 1.8 (dialytic + residual, measured within the past 6 months). • Peritoneal dialysis (adult): Kt/V >= 1.7 (dialytic + residual, measures within the past 4 months).
Denominator	To be included in the denominator for a particular month, patients need to meet the following requirements that month: • Peritoneal dialysis patients: All peritoneal dialysis patients who have been on dialysis for at least 90 days. • Hemodialysis patients: Pediatric (<18 years old) in-center HD patients who have been on dialysis for 90 days or more and dialyzing thrice weekly, adult >=18 years old) patients who have been on dialysis for 90 days or more and dialyzing thrice weekly.	• All adult hemodialysis patients who received dialysis greater than two and less than four times a week (adults, ≥18 years) and all pediatric in-center hemodialysis patients who received dialysis greater than 2 and less than five times a week (pediatric, <18 years), and did not indicate frequent dialysis. • All patients (both HD and PD) who are assigned to the facility for the entire month, and have had ESRD for 90 days or more.

Comment: One commenter expressed concern about the proposed Dialysis Adequacy measure because smaller facilities that would not have had 11 patients in any given dialysis adequacy category under the four individual measures may now be included in the combined measure. Additionally, the commenter recommended that CMS convene a TEP to discuss additional ways in which CMS can include more patients and facilities in the QIP generally.

Response: We proposed to adopt this measure, in part, because we wanted to be able to assess dialysis adequacy in a greater percentage of ESRD patients. We will take the recommendation to convene a TEP in order to explore additional ways to include more ESRD patients in the ESRD QIP into consideration.

[6] Specifications for the Delivered Dose of Dialysis above Minimum—Composite Score measure reviewed by the Measure Applications Partnership are available at *https://www.qualityforum.org/map/* under the document titled ``*Spreadsheet of MAP 2015 Final Recommendations.''*

[7] Specifications for the Dialysis Adequacy clinical measure proposed in the CY 2016 ESRD PPS proposed rule are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Proposed-PY-2019-measure-specs_6-24-15.pdf.*

Comment: A few commenters requested that CMS retain the seven-treatment per month exclusion from the previous dialysis adequacy measures because facilities rarely collect Kt/V for transient patients. One commenter further requested that CMS allow facilities to submit Kt/V collected from an outside source for these patients. Another commenter recommended that CMS define the minimum number of treatment days under the care of a facility for peritoneal dialysis patients when calculating the current peritoneal dialysis adequacy clinical measures, and recommended a threshold of approximately 14 peritoneal dialysis treatment days.

Response: The measure specifications for the proposed Dialysis Adequacy clinical measure exclude from the denominator ''all patients who were not assigned to the facility for the entire month,'' which will have effect of excluding all peritoneal dialysis patients who are treated less than seven times per month and all peritoneal dialysis patients who are not assigned to the facility for the entire month.

Comment: One commenter requested that CMS provide additional information regarding the benchmarks and achievement thresholds for the comprehensive Dialysis Adequacy clinical measure, citing concerns that these values may be difficult to determine because the Kt/V thresholds for the measures within the comprehensive Dialysis Adequacy clinical measure vary across patient age and treatment modality.

Response: Facility performance on the measure will be evaluated in much the same way as facility performance on the dialysis adequacy measure topic that was part of the QIP for three payment years. Kt/V values for a particular patient month will be compared to the threshold for the given modality and patient age, and assigned to numerators and denominators as appropriate. Much like the previously finalized Dialysis Adequacy Measure Topic, numerators and denominators for the four sub-groupings of age and modality will be aggregated together and weighted according to the number of patient months represented.

Comment: Some commenters requested that CMS modify the comprehensive Dialysis Adequacy clinical measure's hemodialysis threshold to account for the higher Kt/V values for nocturnal dialysis patients.

Response: The previously implemented dialysis adequacy measures did not distinguish between types of hemodialysis patients, other than to identify frequency of treatment on a weekly basis, nor was this recommended by Technical Expert Panels convened for the purpose of developing the proposed comprehensive dialysis adequacy measure. As always, we continue an ongoing measure maintenance cycle where these and other recommendations may be considered within the context of available data and existing clinical evidence.

Comment: Several commenters did not support the proposed comprehensive Dialysis Adequacy clinical measure because the measure pools the scores from the four dialysis populations, despite the vast differences between these groups, which make it difficult to accurately assess a facility's quality under the proposed measure. Some of these commenters expressed concerns that the pooled approach may obscure differences in quality of care for pediatric patients, peritoneal dialysis patients, and home hemodialysis patients. Commenters also stated that the effect of one or two outliers may distort the overall quality of care provided at facilities with a small number of patients.

Response: The Dialysis Adequacy Clinical Measure is does not clinically co-mingle peritoneal dialysis and hemodialysis modalities. Peritoneal dialysis patients are assessed based on clinical standards appropriate for these patients, while hemodialysis patients are assessed based on clinical standards appropriate for them. We understand that patient groups that comprise a smaller percentage of a facility's total population will have less impact on the facility's performance score for the Dialysis Adequacy clinical measure; however, failure to incorporate pediatric, peritoneal, and home dialysis patients into the four individual dialysis adequacy measures due to reporting requirements significantly limits the ability to evaluate facility performance for those subgroups. We also note that individual-level data remains available upon request for all QIP measures following calculation of measure scores for a given payment year of the ESRD QIP, should facilities wish to investigate their internal performance while reviewing their Preview Performance Score Report for that year. More granular detail is also available via the annually published Dialysis Facility Reports and the Dialysis Facility Compare tool. Clinically, the proposed measure assesses each patient on clinically appropriate standards, and the measure addresses whether each patient has received adequate dialysis based on that individual's needs. As a result, the performance rate is a description of the rate at which a facility is adequately meeting the dialysis needs of its patients, regardless of their age and modality. We therefore believe that any potential for the proposed measure to ''mask'' facility performance for smaller segments of its population is outweighed by the benefit of including these patients in the measure population.

Comment: Commenters expressed concerns about the Dialysis Adequacy clinical measure because of the concerns raised during the NQF Renal Standing Committee. Specifically, the commenters do not support the measure because the NQF recommended against endorsement.

Response: While the NQF Renal Standing Committee has not yet issued its final report, we understand that the Committee's current recommendation is against endorsement for this measure, because the Committee determined that measure failed the NQF's Importance to Measure and Report criterion. Specifically, the NQF Renal Standing Committee expressed concerns about the strength of evidence supporting the pediatric hemodialysis and peritoneal dialysis Kt/V thresholds established under this measure. However, we continue to believe that including pediatric patients in assessments of dialysis adequacy is critical, because these patients constitute a unique subpopulation of ESRD patients and are often excluded from other ESRD QIP quality measures. Very few facilities treating pediatric patients qualify to receive a score under the current Pediatric Hemodialysis Adequacy and Pediatric Peritoneal Dialysis Adequacy clinical measures, and adopting the single, comprehensive Dialysis Adequacy clinical measure will allow us to capture the quality of care provided to a greater proportion of pediatric patients nationally.

Comment: One commenter did not support adoption of the comprehensive Dialysis Adequacy clinical measure because it includes pediatric patients receiving dialysis three and four times a week when the evidence for the measure is based on patients receiving treatments three times a week.

Response: The 2010 TEP that recommended this measure originally specified the measure to include pediatric patients on dialysis 3 or 4 times per week, based in part on analyses showing that 4 times per week hemodialysis was observed in approximately 5.6 percent of pediatric patient weeks, and nearly 90 percent of pediatric patient weeks reflected either 3 or 4 times per week hemodialysis (based on 2007 Medicare claims data).

Given that this was a significant proportion of patients, the TEP concluded that these patients should all be included in this measure. While the Delivered Dose of Dialysis above Minimum measure under review by the NQF Renal Standing Committee has revised its measure specifications to capture only pediatric hemodialysis patients dialyzing three times per week, we believe it is important to capture as many pediatric patients as possible in the ESRD QIP. There are currently very few measures that focus on the care provided to pediatric ESRD patients, and excluding pediatric hemodialysis patients dialyzing four times per week from the Dialysis Adequacy clinical measure would exclude those patients from all dialysis adequacy assessment. In addition, we believe that collecting data on the quality of care provided to pediatric hemodialysis patients can influence the standard of care provided by all facilities that treat pediatric patients. For these reasons, we are including pediatric hemodialysis patients who dialyze three or four times per week in the Dialysis Adequacy clinical measure.

Comment: Several commenters recommended that CMS adopt modifications for the upper Kt/V threshold recommended by the NQF Renal Standing Committee; specifically, removing the upper Kt/V threshold exclusion due to insufficient evidence supporting the selected values. One commenter argued that the evidence-based threshold should be the only value in the specifications, and the handling of anomalous data should be addressed by measure implementation and operationalization guidance so that patients with spurious Kt/V values are excluded from the measure calculations.

Response: The proposed Dialysis Adequacy clinical measure does not include upper thresholds for patients' Kt/V (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Proposed-PY±2019-measure-specs_6-24-15.pdf*), and the Dialysis Adequacy measure under review by the NQF Renal Standing Committee was also revised to remove these upper thresholds.

Comment: One commenter requested that CMS provide additional details about the technical specifications for the comprehensive Dialysis Adequacy clinical measure in the ESRD Measures Manual.

Response: We intend to incorporate the Dialysis Adequacy clinical measure into the CMS ESRD Measures Manual before the beginning of the measure's performance period in CY 2017. The Measures Manual, will provide detailed measure specifications for all measures used in the ESRD QIP and other CMS ESRD programs, such as Dialysis Facility Compare, and will be updated in the future as new measures are implemented, such as the comprehensive Dialysis Adequacy clinical measure.

Comment: One commenter recommended that CMS include residual renal function in dose calculations for hemodialysis patients only if the urine collection used to measure it was performed within the last 90 days.

Response: The current dialysis adequacy measures do not currently include residual renal function as part of the NQF endorsed specifications, and the proposed measure retains this form. In addition, the Technical Expert Panels convened for the purpose of developing these measures have not recommended the inclusion of residual renal function to date. As always, we maintain an ongoing measure maintenance cycle where these and other recommendations may be considered within the context of available data and existing clinical evidence.

Comment: One commenter expressed concern about the impact of peritoneal dialysis patients' noncompliance with treatment protocols on facility performance. Specifically, the commenter recommended that facilities should either receive credit for their efforts to get peritoneal dialysis patients to visit the facility in a given month, or that noncompliant peritoneal dialysis patients should be excluded from the facilities' measure scores.

Response: Our quality measures do not currently assess patient compliance directly, as currently available data sources are unable to capture the information. Moreover, while we recognize that some patients may follow a course of treatment less assiduously than others, we believe it remains the facility's responsibility to continue reaching out to these patients for the purpose improving their quality of care.

For these reasons, we are finalizing the single comprehensive Dialysis Adequacy clinical measure as proposed, beginning in PY 2019.

c. Reporting Measures Proposed, Beginning with the PY 2019 ESRD QIP

i. Proposed Ultrafiltration Rate Reporting Measure

The ultrafiltration rate measures the rapidity with which fluid (ml) is removed at dialysis per unit (kg) body weight in unit (hour) time. A patient's ultrafiltration rate is under the control of the dialysis facility and is monitored throughout a patient's hemodialysis session. Studies suggest that higher ultrafiltration rates are associated with higher mortality and higher odds of an ''unstable'' dialysis session,[8] and that rapid rates of fluid removal during dialysis can precipitate events such as intradialytic hypotension, subclinical yet significantly decreased organ perfusion, and in some cases myocardial damage and heart failure.

Section 1881(h)(2)(A)(iv) gives the Secretary authority to adopt other measures for the ESRD QIP that cover a wide variety of topics. Section 1881(h)(2)(B)(ii) of the Act states that ''In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of Act [in this case NQF], the Secretary may specify a measure that is not so endorsed so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.'' We have given due consideration to endorsed measures, as well as those adopted by a consensus organization. Because no NQF-endorsed measures or measures adopted by a consensus organization on ultrafiltration rates currently exist, we proposed to adopt the Ultrafiltration Rate reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

We proposed to adopt a measure that is based on Measure Applications Partnership #XAHMH, ''Ultrafiltration Rate Greater than 13 ml/kg/hr'' (''Ultrafiltration Rate measure''). This measure assesses the percentage of patient-months for patients with an ultrafiltration rate greater than 13 ml/kg/hr. The Measure Applications Partnership expressed conditional support for the Ultrafiltration Rate measure, noting it would ''consider the measure for inclusion in the program once it has been reviewed for endorsement.'' The measure upon which our proposed measure is based is currently under review for endorsement by NQF; however, we believe the

[8] Flythe SE., Kimmel SE., Brunelli SM. Rapid fluid removal during dialysis is associated with cardiovascular morbidity and mortality. Kidney International (2011) Jan; 79(2):250–7. Flythe JE, Curhan GC, Brunelli SM. Disentangling the ultrafiltration rate—mortality association: The respective roles of session length and weight gain. Clin J Am Soc Nephrol. 2013 Jul;8(7):1151–61. Movilli, E *et al.* ''Association between high ultrafiltration rates and mortality in uraemic patients on regular hemodialysis. A 5-year prospective observational multicenter study.'' Nephrology Dialysis Transplantation 22.12(2007): 3547–3552.

measure is ready for adoption because it has been fully tested for reliability and addresses a critical aspect of patients' clinical care not currently addressed by the ESRD QIP measure set.

For PY 2019 and future payment years, we proposed that facilities must report an ultrafiltration rate for each qualifying patient at least once per month in CROWNWeb. Qualifying patients for this proposed measure are defined as patients 18 years of age or older, on hemodialysis, and who are assigned to the same facility for at least the full calendar month (for example, if a patient is admitted to a facility during the middle of a month, the facility will not be required to report for that patient for that month). We further proposed that facilities will be granted a one month period following the calendar month to enter this data. For example, we would require a facility to report ultrafiltration rates for January 2017 on or before February 28, 2017. Facilities would be scored on whether they successfully report the required data within the timeframe provided, not on the values reported. Technical specifications for the Ultrafiltration Rate reporting measure can be found at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: While several commenters supported the proposal to adopt the Ultrafiltration Rate reporting measure or the concept of an ultrafiltration rate measure in the ESRD QIP, many commenters did not support the specific measure proposed. Some commenters stated that ultrafiltration rates are highly variable even within individual patients, and it is unclear whether the proposed measure can influence quality of care without impacting the clinical judgment of ESRD providers. Many commenters also stated that the proposed measure is subject to ''gaming'' concerns because it relies on a single data point per month, as opposed to other ultrafiltration rate measures, such as NQF #2701, Avoidance of Utilization of High Ultrafiltration rate (≥13 ml/kg/hr), which uses an average across all dialysis treatments provided over the course of a week to determine a patient's average ultrafiltration rate. These commenters further argued that the proposed Ultrafiltration Rate reporting measure's lack of any exclusion criteria or data collection regarding patients with longer time on dialysis also hampers the proposed measure's ability to evaluate the quality of care provided to ESRD patients.

Response: We appreciate the many comments we received on the Ultrafiltration Rate reporting measure. As a result of the significant concerns expressed about the measure, we have decided not to finalize the measure at this time. We will consider alternate approaches to collecting patient ultrafiltration rate data in the future.

For these reasons, we are not finalizing the proposed Ultrafiltration Rate reporting measure for the ESRD QIP.

ii. Proposed Full-Season Influenza Vaccination Reporting Measure

According to the Centers for Disease Control and Prevention (CDC), seasonal influenza, which occurs between October and March/April of the following year, is associated with approximately 20,000 deaths [9] and 226,000 hospitalizations annually.[10] While overall rates of influenza infection are highest among children, rates of serious illness and mortality are highest among adults aged 65 years or older, children aged two or younger, and immunocompromised patients such as patients with ESRD. Observational data have found associations between influenza vaccination and reduced mortality and hospitalization in this patient population. Specifically, multiple studies have found that vaccinated patients have significantly lower odds of all-cause mortality and modestly lower odds of all-cause hospitalization compared to unvaccinated patients.[11] However, influenza vaccination rates in the ESRD population have historically been lower than the Healthy People 2020 goal of 70 percent of both pediatric and adult populations in the United States,[12] with recent reports from the U.S. Renal Data System and Dialysis Facility Reports showing vaccination rates of 67 percent and 68 percent, respectively, among ESRD patients for the 2011–2012 season.[13] Based on these findings, we believe that encouraging closer evaluation of patients' influenza vaccination status in the dialysis facility will increase the number of patients with ESRD who receive an influenza vaccination and increase influenza vaccination rates in this population, which will in turn improve patient health and well-being.

We proposed to use a measure that is based on ''ESRD Vaccination—Full-Season Influenza Vaccination'' (Measure Applications Partnership #XDEFM). This measure assesses the percentage of ESRD patients ≥ 6 months of age on October 1 and on chronic dialysis ≥ 30 days in a facility at any point between October 1 and March 31 who either: (1) Received an influenza vaccination; (2) were offered but declined the vaccination; or (3) were determined to have a medical contraindication. The Measure Applications Partnership conditionally supported the use of the ESRD Vaccination—Full-Season Influenza Vaccination measure in the ESRD QIP in its January 2014 Pre-Rulemaking Report because ''influenza vaccination is very important for dialysis patients.'' Nevertheless, the Measure Applications Partnership declined to give the measure full support because it was not sure that the measure was more suitable to drive improvement than NQF #0226: ''Influenza Immunization in the ESRD Population (Facility Level)''. We have reviewed the measure specifications for NQF #0226 and determined that it is not appropriate to use as the basis for a reporting measure because the denominator statement of NQF #0226 excludes all patients for whom data during the flu season is incomplete, potentially excluding patients who died from influenza, but might not have died if they had received an influenza vaccination. We therefore believe it is more appropriate to adopt a reporting measure based on the ESRD Vaccination—Full-Season Influenza Vaccination measure (Measure Applications Partnership #XDEFM) because this measure includes patients who died from influenza, but might not have died if they had received an influenza vaccination, and we believe it is important to include such patients in an influenza immunization clinical measure for the ESRD QIP, should we

[9] Centers for Disease Control and Prevention (CDC). Estimates of Deaths Associated with Seasonal Influenza—United States, 1976–2007. *MMWR* (2010) 59:33. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5933a1.htm.*

[10] Centers for Disease Control and Prevention (CDC). Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*2010a;59(RR–8):1–62.

[11] Bond TC, Spaulding AC, Krisher J, et al. Mortality of dialysis patients according to influenza and pneumococcal vaccination status. Am J Kidney Dis. 2012;60:959–65; Gilbertson DT, Unruh M, McBean AM, et al. Influenza vaccine delivery and effectiveness in end-stage renal disease. Kidney Int. 2003;63:738–43.

[12] *http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives* (Healthy People 2020 IID–12.11 and IID–12.12).

[13] US Renal Data System, USRDS 2014 Annual Data Report: An overview of the epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2014.

propose to adopt such a measure in the future.

For these reasons, we proposed to adopt a reporting measure based on ''ESRD Vaccination—Full-Season Influenza Vaccination'' (''Full-Season Influenza Vaccination reporting measure'') so that we can collect data that we can use in the future to calculate both achievement and improvement scores, should we propose to adopt a clinical version of this measure in future rulemaking.

Section 1881(h)(2)(B)(ii) of the Act states that ''In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act [in this case NQF], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.'' Because we have given due consideration to endorsed measures, as well as those adopted by a consensus organization, and determined it is not practical or feasible to adopt those measures in the ESRD QIP, we proposed to adopt the Full-Season Influenza Vaccination reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act.

For PY 2019 and future payment years, we proposed that facilities must report one of the following conditions in CROWNWeb once per performance period, for each qualifying patient (defined below):

1. If the patient received an influenza vaccination:

a. Influenza Vaccination Date

b. Where Influenza Vaccination Received: (1) Documented at facility; (2) Documented outside facility; or (3) Patient self-reported outside facility

2. If the patient did not receive an influenza vaccination:

a. Reason:

i. Already vaccinated this flu season

ii. Medical Reason: Allergic or adverse reaction

iii. Other medical reason

iv. Declined

v. Other reason

We note that while facilities are expected to retain patient influenza immunization documentation for their own records, facilities are not required to supply this documentation to CMS under the Full-Season Influenza Vaccination reporting measure.

For this measure, a qualifying patient would be defined as a patient aged six months or older as of October 1 who has been on chronic dialysis for 30 or more days in a facility at any point between October 1 and March 31. This measure would include in-center hemodialysis, peritoneal dialysis, and home dialysis patients. This proposed measure would capture the same data described in ''ESRD Vaccination—Full-Season Influenza Vaccination'', but we would require that facilities report the data on or before May 15 following the performance period for that year. We believe this reporting deadline will ensure that facilities have sufficient time to collect and enter data for all qualifying patients following the influenza season, and aligns this reporting effort with that of the NHSN Healthcare Personnel Influenza Vaccination reporting measure finalized in the CY 2015 ESRD PPS final rule for PY 2018 (79 FR 66206 through 66208). Second, we proposed to score facilities based on whether they successfully report the data, and not based on the measure results. Technical specifications for the Full-Season Influenza Vaccination reporting measure can be found at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.*

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: While several commenters supported the proposal to adopt the Full-Season Influenza Vaccination reporting measure or the concept of a patient-level influenza vaccination measure in the ESRD QIP, many commenters did not support the specific measure proposed. A number of these commenters recommended that CMS adopt a reporting measure that aligns more closely with NQF #0226: Influenza Immunization in the ESRD Population, arguing that the NQF-endorsed measure would better encourage timely vaccination of patients with ESRD and avoid penalizing facilities for patients who die but for whom time remained to meet the measure specifications. Some commenters also expressed concern about the conditions provided for reporting in CROWNWeb because their apparent overlap may result in inaccurate reporting, and other commenters recommended alternative conditions to capture instances such as hospitalized patients. Many commenters also stated that the proposed measure's timeline does not properly account for the reality that the influenza vaccination often becomes available before October 1, and may therefore result in unintended negative consequences for facilities that vaccinate patients before the performance period begins. Other commenters strongly recommended CMS use the NHSN system instead of CROWNWeb to collect patient influenza immunization data because facilities already use NHSN for other data reporting and adding the proposed measure to NHSN would provide reporting consistency, as well as allow a larger proportion of the ESRD community to access data reported for the measure while simplifying the requirements for ESRD facilities.

Response: We appreciate the many comments we received on the Full-Season Influenza Vaccination reporting measure. As a result of the significant concerns expressed about the measure, we have decided not to finalize the measure at this time. We will consider alternative methods of collecting these important patient care data in the future.

For these reasons, we are not finalizing the proposed Full-Season Influenza Vaccination reporting measure for the ESRD QIP.

3. Performance Period for the PY 2019 ESRD QIP

Section 1881(h)(4)(D) of the Act requires the Secretary to establish the performance period with respect to a payment year, and that the performance period occur prior to the beginning of such year. We proposed to establish CY 2017 as the performance period for the PY 2019 ESRD QIP for all but the influenza vaccination measures because it is consistent with the performance period we have historically used for these measures and accounts for seasonal variations that might affect a facility's measure score. We proposed that the performance period for both the NHSN Healthcare Personnel Influenza Vaccination reporting measure and the proposed Full-Season Influenza Vaccination reporting measure will be from October 1, 2016 through March 31, 2017, because this period spans the length of the 2016–2017 influenza season.

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: Several commenters supported the proposed performance period for the PY 2019 ESRD QIP.

Response: We thank the commenters for their support.

Comment: Two commenters recommended that the performance period for both Influenza Vaccination measures be changed to encompass the earliest possible date that the influenza vaccine may be available in a given calendar year. They argued that operationally, facilities begin to vaccinate patients as soon as the vaccine

is available, which could be as early as August. This would be consistent with the CDC's NHSN Flu Vaccine Protocol which encompasses ''the time from when the vaccine became available through March 31 of the following year.''

Response: We thank the commenters for their comments, and note that, as discussed above, we are not finalizing the Full-Season Influenza Vaccination reporting measure at this time. We note, however, that the performance period for the NHSN Healthcare Personnel Influenza Vaccination reporting measure does not restrict facilities to reporting only vaccinations received after October 1; instead, it establishes the period for which the facility must report HCP vaccination status. As a result, we encourage facilities to report vaccination statuses for all HCPs working at the facility and were vaccinated both before and after October 1.

Comment: One commenter expressed concerns that small providers who manually submit data are unduly burdened by the requirements of the ESRD QIP and expressed that with varied performance periods among quality measures, these requirements become very time consuming and burdensome.

Response: For all but one measure in the ESRD QIP, we have used the calendar year as the performance period. The remaining measure, the NHSN HCP Influenza Vaccination reporting measure, uses a performance period of October 1 of the preceding year through March 31 of the following year to reflect the length and timing of the applicable influenza season. We believe this differing performance period is necessary to ensure the timely administration and monitoring of influenza vaccinations, and is not unduly burdensome on facilities.

For these reasons, we are finalizing the PY 2019 performance periods as proposed.

4. Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2019 ESRD QIP

Section 1881(h)(4)(A) of the Act provides that ''the Secretary shall establish performance standards with respect to measures selected . . . for a performance period with respect to a year.'' Section 1881(h)(4)(B) of the Act further provides that the ''performance standards . . . shall include levels of achievement and improvement, as determined appropriate by the Secretary.'' We use the performance standards to establish the minimum score a facility must achieve to avoid a Medicare payment reduction. We use achievement thresholds and benchmarks to calculate scores on the clinical measures.

a. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures in the PY 2019 ESRD QIP

For the same reasons stated in the CY 2013 ESRD PPS final rule (77 FR 67500 through 76502), we proposed for PY 2019 to set the performance standards, achievement thresholds, and benchmarks for the clinical measures at the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2015, because this will give us enough time to calculate and assign numerical values to the proposed performance standards for the PY 2019 program prior to the beginning of the performance period. We continue to believe these standards will provide an incentive for facilities to continuously improve their performance, while not reducing incentives to facilities that score at or above the national performance rate for the clinical measures.

We sought comments on these proposals. The comments and our responses are set forth below.

Comments: Many commenters supported the proposed performance standards, achievement thresholds, and benchmarks for the PY 2019 ESRD QIP being set at the 50th, 15th and 90th percentiles respectively.

Response: We thank the commenters for their support.

For these reasons, we are finalizing the PY 2019 performance standards, achievement thresholds, and benchmarks as proposed.

b. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Proposed for the PY 2019 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the proposed performance standards for the clinical measures, because we do not yet have data from CY 2015 or the first portion of CY 2016. We will publish values for the clinical measures, using data from CY 2015 and the first portion of CY 2016, in the CY 2017 ESRD PPS final rule.

c. Performance Standards for the PY 2019 Reporting Measures

In the CY 2014 ESRD PPS Final Rule, we finalized performance standards for the Anemia Management and Mineral Metabolism reporting measures (78 FR 72213). In the CY 2015 ESRD PPS Final Rule, we finalized our proposal to modify the measure specifications for the Mineral Metabolism reporting measure to allow facilities to report either serum phosphorus data or plasma phosphorus data for the Mineral Metabolism reporting measure (79 FR 66191). We did not propose any changes to these policies for the PY 2019 ESRD QIP.

In the CY 2015 ESRD PPS Final Rule, we finalized performance standards for the Screening for Clinical Depression and Follow-Up, Pain Assessment and Follow-Up, and NHSN Healthcare Provider Influenza Vaccination reporting measures (79 FR 66209). We did not propose any changes to these policies.

For the Ultrafiltration Rate reporting measure, we proposed to set the performance standard as successfully reporting an ultrafiltration rate for each qualifying patient in CROWNWeb on a monthly basis, for each month of the reporting period.

For the Full-Season Influenza Vaccination reporting measure, we proposed to set the performance standard as successfully reporting one of the above-listed vaccination statuses for each qualifying patient in CROWNWeb on or before May 15th of the performance period.

We sought comments on these proposals. We did not receive comments on these proposals, and are therefore finalizing them as proposed for all measures except the Ultrafiltration Rate reporting measure and the Full-Season Influenza Vaccination reporting measure, which we are not finalizing.

5. Scoring the PY 2019 ESRD QIP

a. Scoring Facility Performance on Clinical Measures Based on Achievement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on achievement (78 FR 72215). Under this methodology, facilities receive points along an achievement range based on their performance during the performance period for each measure, which we define as a scale between the achievement threshold and the benchmark. In determining a facility's achievement score for each clinical measure under the PY 2019 ESRD QIP, we proposed to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. The facility's achievement score would be calculated by comparing its performance on the measure during CY 2017 (the proposed performance period) to the achievement threshold and benchmark (the 15th and 90th

percentiles of national performance on the measure in CY 2015).

b. Scoring Facility Performance on Clinical Measures Based on Improvement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on improvement (78 FR 72215 through 72216). In determining a facility's improvement score for each measure under the PY 2019 ESRD QIP, we proposed to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. Under this methodology, facilities receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We proposed to define the improvement threshold as the facility's performance on the measure during CY 2016. The facility's improvement score would be calculated by comparing its performance on the measure during CY 2017 (the proposed performance period) to the improvement threshold and benchmark.

We sought comment on these proposals. The comments and our responses are set forth below.

Comment: One commenter supported the proposal for scoring the PY 2019 ESRD QIP measures.

Response: We thank the commenter for its support.

Comment: Some commenters expressed concerns about the ESRD QIP scoring methodology. One commenter argued that the scoring methodology is too complex, such that facilities are not afforded the opportunity to make immediate adjustments to care when minimum scores are not met. Another commenter noted that small and medium-sized facilities with limited resources find the increasingly complicated formulas difficult to understand, and occasionally have to contract with outside firms to understand how proposed changes will affect them, predict how they will perform, and their results.

Response: The ESRD QIP scoring methodology is designed to make facility measure scores and TPSs as fair as possible, given the wide range of facility sizes and populations across the country, and we believe that attempting to further simplify the methodology may result in unfair scoring for facilities. In an effort to help facilities better understand the ESRD QIP's scoring methodology, we provide multiple resources that further elucidate the methodology, including calculation examples in preamble text, National Provider Calls, and the Preview Performance Score Report. We encourage facilities experiencing difficulty in understanding the ESRD QIP's scoring methodology to contact the program for assistance.

We also understand that the current scoring methodology does not allow facilities to calculate their current performance scores in real time for use in their quality improvement efforts. We are looking into opportunities to allow facilities this level of interaction with their ESRD QIP data, but are currently unable to do so due to claims processing timelines and system limitations.

Comment: Commenter expressed concern that that the current ESRD QIP scoring methodology is unfair to smaller facilities because when a small facility and a large facility provide the same quality of care to patients, the lower census facility will lose a higher proportion of points in the calculation. Commenter argued that, as a result of this calculation and weighting issue, it is inappropriate to compare small facilities' performance to large facilities' performance.

Response: We acknowledge that the current scoring methodology may result in a small number of outlier patients unduly impacting the facility's score. In order to alleviate the potential negative impact of a small number of patients on small facilities' scores, we have adopted the Small Facility Adjuster, which provides a positive adjustment to eligible small facilities' measure scores. We believe this adjustment is sufficient to counteract the negative effects of a small patient census on facility scores, but will continue to assess the appropriateness of additional measures to ensure accuracy in measure scoring for small facilities.

For these reasons, we are finalizing the achievement and improvement scoring methodologies for clinical measures in the PY 2019 ESRD QIP as proposed.

c. Scoring the ICH CAHPS Clinical Measure

In the CY 2015 ESRD PPS final rule, we finalized a policy for scoring performance on the ICH CAHPS clinical measure based on both achievement and improvement (79 FR 66209 through 66210). Under this methodology, facilities will receive an achievement score and an improvement score for each of the three composite measures and three global ratings in the ICH CAHPS survey instrument. A facility's ICH CAHPS score will be based on the higher of the facility's achievement or improvement score for each of the composite measures and global ratings, and the resulting scores on each of the composite measures and global ratings will be averaged together to yield an overall score on the ICH CAHPS clinical measure. For PY 2019, the facility's achievement score would be calculated by comparing where its performance on each of the three composite measures and three global ratings during CY 2017 falls relative to the achievement threshold and benchmark for that measure and rating based on CY 2015 data. The facility's improvement score would be calculated by comparing its performance on each of the three composite measures and three global ratings during CY 2017 to its performance rates on these items during CY 2016.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: One commenter supported the proposed methodology for scoring the ICH CAHPS clinical measure.

Response: We thank the commenter for its support.

Comment: One commenter expressed concerns about the length of time it is taking for the ICH CAHPS measure to become a clinical performance measure in the QIP.

Response: The ICH CAHPS was first incorporated into the ESRD QIP measure set as a reporting measure for PY 2014; performance on this reporting measure has been included in facility Total Performance Scores for the past three years of the program, and will continue through PY 2017. With each year, we have continued to develop the baseline data and facility experience necessary to implement a clinical measure on ICH CAHPS performance. We agree that the ICH CAHPS clinical measure finalized for PY 2018 will have a greater impact on clinical practice by holding facilities accountable for their actual performance. As discussed in the CY 2015 ESRD PPS final rule with comment period (79 FR 66198), we believe this gradual ramp-up of the ICH CAHPS measure was necessary to ensure facilities are sufficiently versed in the survey administration process to be reliably evaluated on the measure beginning with performance in CY 2016.

Comment: One commenter urged CMS to consider breaking out questions 10 and 12 from the ICH CAHPS survey into separate measures for scoring and reporting. (''Did the dialysis center staff listen carefully to you?'' and ''Did the dialysis center staff show respect for what you had to say?'').

Response: The current ICH CAHPS survey is divided into two categories, global ratings and composite measures. Questions 10 and 12 are currently part of the Quality of Dialysis Center Care

and Operations Composite measure, which integrates answers from a total of 17 individual survey items, all related to the care provided by the dialysis center and to dialysis center operations. We believe this composite measure, which examines the complete ICH CAHPS survey, appropriately addresses a broad range of concerns, and is therefore more reflective of the full care experience of patients at a facility, than a measure would be if it looked at one single question from the survey. However, we encourage individual facilities to monitor responses to individual items as part of their efforts to identify opportunities for quality improvement.

Comment: One commenter requested that CMS further clarify how the scores from each of the two survey administrations will be used in scoring the ICH CAHPS clinical measure.

Response: Under the ICH CAHPS clinical measure, eligible facilities will perform two survey administrations per year, one in the spring and one in the fall. At the conclusion of each of these survey administrations, composite scores and global ratings will be calculated for each survey. The results will then be averaged across the two surveys for the year, and the resulting averages will be used in the calculation of both achievement and improvement scores.

For these reasons, we are finalizing the scoring methodology for the ICH CAHPS clinical measure as proposed for the PY 2019 program.

d. Calculating Facility Performance on Reporting Measures

In the CY 2013 ESRD PPS final rule, we finalized policies for scoring performance on the Anemia Management and Mineral Metabolism reporting measures in the ESRD QIP (77 FR 67506). We did not propose any changes to these policies for the PY 2019 ESRD QIP.

In the CY 2015 ESRD PPS final rule, we finalized policies for scoring performance on the Clinical Depression Screening and Follow-Up, Pain Assessment and Follow-Up, and NHSN Healthcare Provider Influenza Vaccination reporting measures (79 FR 66210 through 66211). We did not propose any changes to these policies.

With respect to the Ultrafiltration Rate reporting measure, we proposed to score facilities with a CCN Open Date before July 1, 2017 using the same formula previously finalized for the Mineral Metabolism and Anemia Management reporting measures (77 FR 67506):

$$\left[\frac{(\#\text{ months successfully reporting data})}{(\#\text{ eligible months})} \times 12\right] - 2$$

As with the Anemia Management and Mineral Metabolism reporting measures, we would round the result of this formula (with half rounded up) to generate a measure score from 0–10.

With respect to the Full-Season Influenza Immunization reporting measure, we proposed to score facilities with a CCN Open Date before January 1, 2017 based on the proportion of eligible patients for which the facility successfully submits one of the vaccination status indicators listed above by the May 15, 2017 deadline using the following formula:

$$\left[\frac{\left(\begin{array}{c}\text{No. patients for whom facility reports vacc.}\\ \text{status during the performance period}\end{array}\right)}{\left(\begin{array}{c}\text{No. of eligible patients during the performance}\\ \text{period}\end{array}\right)}\right]$$

We sought comments on these proposals. The comments and our responses are set forth below.

Comment: One commenter expressed concern about how CMS would account for patients who are no longer in the facility when the vaccination reporting is due for the Full-Season Influenza Vaccination reporting measure.

Response: We thank the commenter for its comment. However, we are not finalizing the Full-Season Influenza Vaccination reporting measure at this time.

For these reasons, we are finalizing the scoring methodologies for all reporting measures except the Ultrafiltration Rate reporting measure and the Full-Season Influenza Vaccination reporting measure, which we are not finalizing.

6. Weighting the Clinical Measure Domain and Total Performance Score

i. Weighting the Clinical Measure Domain for PY 2019

In the CY 2015 ESRD PPS final rule, we finalized policies regarding the criteria we would use to assign weights to measures in a facility's Clinical Measure Domain score (79 FR 66214 through 66216). Specifically, we stated that in deciding how to weight measures and measure topics within the Clinical Measure Domain, we would take into consideration: (1) The number of measures and measure topics in a proposed subdomain; (2) how much experience facilities have had with the measures; and (3) how well the measures align with CMS' highest priorities for quality improvement for patients with ESRD.

In the same rule, we finalized the Dialysis Adequacy measure topic and Vascular Access Type measure topic's weights for PY 2018 at 18 percent of a facility's Clinical Measure Domain score because facilities have substantially more experience with the Dialysis Adequacy measure topic as compared to the other measures in the Clinical Care subdomain (79 FR 66214).

Beginning in PY 2019, we proposed to remove the Dialysis Adequacy measure topic and replace it with the Dialysis Adequacy clinical measure. Because this proposed measure is a composite of

the measures previously included in the Dialysis Adequacy measure topic, with the same Kt/V thresholds currently used for those measures, we believe that facilities are already familiar with the concepts underlying this proposed measure and that the measure should be weighted at 18 percent of a facility's Clinical Measure Domain score. We are not proposing any further changes to the weighting for the remaining clinical measures and measure topics within the Clinical Measure Domain because the previously finalized weights are aligned with the criteria used to establish measure and measure topic weights. For these reasons, we proposed to use the following weighting system in Table 25 below for calculating a facility's Clinical Measure Domain score beginning in PY 2019.

TABLE 25—PROPOSED CLINICAL MEASURE DOMAIN WEIGHTING FOR THE PY 2019 ESRD QIP

Measures/Measure topics by subdomain	Measure weight in the clinical measure domain score
Safety Subdomain	**20%**
NHSN Bloodstream Infection measure	20%
Patient and Family Engagement/Care Coordination Subdomain	**30%**
ICH CAHPS measure	20%
SRR measure	10%
Clinical Care Subdomain	**50%**
STrR measure	7%
Dialysis Adequacy measure	18%
Vascular Access Type measure topic	18%
Hypercalcemia measure	7%

We sought comments on this proposal for weighting a facility's Clinical Measure Domain score. The comments and our responses are set forth below.

Comment: Two commenters supported the proposed measure weights within the clinical measure domain, as well as the proposal to weight the clinical measure domain at 90 percent of a facility's TPS.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS adopt three additional criteria for determining appropriate weights for clinical measures within the clinical measure domain: (1) Strength of evidence; (2) opportunity for improvement; and (3) clinical significance. The commenter also urged CMS to consult with the dialysis community when determining measure weights for the ESRD QIP.

Response: We agree with the commenter that these criteria encompass important considerations for evaluating measures. As stated in the CY 2015 ESRD PPS final rule with comment period (79 FR 66216), we take these criteria into account when making decisions about whether to adopt a measure in the ESRD QIP, because it would be inappropriate to adopt a measure that did not meet these criteria. Based on this understanding, we developed the three criterion discussed above for determining subdomain weighting within the Clinical Measure Domain (80 FR 37849). We believe these criteria account for the programmatic and operational concerns associated with scoring facilities on ESRD QIP while also reflecting our focus on improving the quality of care provided to ESRD patients. This analysis also implicitly includes a review of the strength of the clinical evidence supporting the measure, the opportunity for improvement among facilities, and the clinical significance of the measure because these issues are inextricably linked with an assessment of the measure's appropriateness and importance of measurement within the ESRD QIP. Because the additional criteria recommended by the commenter are used as a threshold for adopting ESRD QIP measures and are subcomponents of the three previously finalized measure weighting criteria, we do not believe it would be appropriate to also factor these criteria into decisions about how much weight to give measures in a facility's Clinical Domain Score.

In addition, we currently give the industry an opportunity to provide input into the ESRD QIP measure and domain weights by proposing a weighting scheme each year and responding to comments received.

Comment: One commenter expressed concerns with the proposed changes to the measure domain weights because ICH CAHPS clinical measure scores will be paired with a readmission penalty. The commenter stated that ICH CAHPS scores should stand alone in their own Patient Experience domain in order to avoid denigrating the importance of the patient feedback survey.

Response: As discussed in the CY 2015 ESRD PPS final rule with comment period, we combined the NQS goals of Care Coordination and Patient- and Caregiver-Centered Experience of care into one subdomain because we believe the two goals complement one another (79 FR 66214). ''Care Coordination'' refers to the NQS goal of promoting effective communication and coordination of care, while ''Patient- and Caregiver-Centered Experience of Care'' refers to the NQS goal of ensuring that each patient and family is engaged as a partner in care. In order to engage patients and families as partners, we believe that effective communication and coordination of care must coexist, and that patient and family engagement cannot occur independently of effective communication and care coordination. We therefore believe it is appropriate to combine measures of care coordination with those of patient and family engagement for the purposes of calculating a facility's clinical measure domain score.

In addition, we note that the SRR clinical measure receives substantially less weight than the ICH CAHPS clinical measure in the Patient and Family Engagement/Care Coordination subdomain. The SRR clinical measure is weighted at 10 percent of a facility's clinical measure domain score, whereas the ICH CAHPS clinical measure is weighted at 20 percent of a facility's clinical measure domain score, making the ICH CAHPS clinical measure's weight one of the largest components of a facility's clinical measure domain score. We therefore believe that including both of these measures in a single subdomain does not denigrate the importance of the ICH CAHPS survey. We will continue to assess the appropriateness of this subdomain combination as the ICH CAHPS and SRR clinical measures are implemented in the ESRD QIP.

Comment: Two commenters did not support the proposed weighting of the clinical measure domain, arguing that the Vascular Access Type measures and Dialysis Adequacy measure should be weighted higher than the NHSN BSI clinical measure due to issues associated with implementing and scoring the NHSN BSI clinical measure. Additionally, they argued that because Vascular Access Type is the measure that is most actionable for facilities, it should be weighted greater than other measures.

Response: We thank the commenters for their recommendation regarding the weighting of the NHSN BSI clinical measure versus the Vascular Access Type measure topic and Dialysis Adequacy measure. However, we believe the technical issues associated with implementation of the NHSN BSI clinical measure noted by the commenters are now resolved and should not impact future payment years.

We do not believe that increasing the weight of the Vascular Access Type

measure topic and Dialysis Adequacy clinical measure is appropriate at this time. As stated in the CY 2015 ESRD PPS final rule with comment period (79 FR 66215 through 66216), improving patient safety and reducing bloodstream infections in patients with ESRD is one of our highest priorities, and facilities have a good deal of experience with the NHSN BSI clinical measure. As a result, the NHSN BSI clinical measure is weighted at 20 percent of a facility's TPS, the highest allocation provided to measures within the clinical measure domain. However, we also note that the Vascular Access Type measure topic and Dialysis Adequacy clinical measure are also highly weighted within the Clinical Measure Domain at 18 percent of the Clinical Measure Domain each, to reflect the fact that facilities have substantially more experience with this measure and measure topic than the other measures in the Clinical Care subdomain. We therefore believe that the weight assigned to these measures within the Clinical Measure Domain is appropriate for the PY 2019 ESRD QIP. We will continue to assess the appropriateness of this weighting allocation for future years of the Program.

Comment: Two commenters urged CMS to place more emphasis on safety in dialysis facilities by increasing the weight of the Safety Subdomain. One commenter requested that CMS assign greater weight to the Safety Subdomain because patient safety is more aligned with facility quality initiatives and can be more readily controlled by facility staff.

Response: We agree that improving patient safety is of the utmost importance in the ESRD community; however, this is only one of the criteria established for determining the weight of subdomains within the Clinical Measure Domain. The Safety Subdomain contains only one measure, the NHSN BSI clinical measure, and the NHSN BSI clinical measure is weighted at 20 percent of the Clinical Measure Domain score, which is the highest weighting allocation for a single measure under the Clinical Measure Domain. Reallocating weight from the Patient and Family Engagement/Care Coordination and Clinical Care subdomains to further increase the Safety subdomain's prominence in the Clinical Measure Domain is inappropriate because doing so would diminish the remaining measures' importance in facility score, and would not accurately reflect our measure weighting prioritization criteria. We therefore believe the Safety subdomain's current weight is appropriate at this time. We will continue to assess the appropriateness of this weighting allocation for future years of the program.

Comment: One commenter did not support weighting the ICH CAHPS clinical measure at 20 percent of the Clinical Measure Domain because of the burden it imposes on small facilities; the difficulty in implementing changes based on survey results before the next semiannual survey is performed; and the survey fatigue it causes patients, which may in turn impact patient responses.

Response: While we understand that the ICH CAHPS survey may be burdensome for facilities, we believe that measuring patient experience can lead to quality improvement, which may in turn lead to better outcomes. In addition, the ICH CAHPS survey supports the National Quality Forum's strategy priorities of Effective Communication and Care Coordination and Person and Family-Centered Care, as well as the Institute of Medicine's six specific aims for improvement. Furthermore, we note that the case minimum for the ICH CAHPS clinical measure is 30 qualifying patients in the year preceding the performance period. This case minimum is much higher than the 11 qualifying patient minimum used for the majority of the ESRD QIP clinical measures. We believe these thresholds help to decrease the burden on small facilities by exempting from the measure those facilities that do not regularly treat enough qualifying patients, and further avoids unduly impacting small facilities' scores by also exempting otherwise eligible small facilities who do not receive enough completed surveys during the performance period.

Comment: One commenter supported the proposal for weighting the Clinical Measure Domain and the Total Performance Score.

Response: We thank the commenter for its support.

Comment: One commenter expressed concern that the Clinical Measure Domain weighting policy places smaller facilities at a disadvantage in scoring. The commenter noted that when a larger facility and a small facility provide comparable care to patients for a given measure but the small facility is not eligible to receive a score on that measure because it has too few patients, the reallocated measure weight may cause the small facility to lose points from its TPS. The commenter requested that CMS calculate facilities' TPS based on the facilities' performance on the ESRD QIP measures, regardless of facility size and avoid adjusting measure weighting when the facility is not eligible for some measure due to low facility volume.

Response: We thank the commenter for sharing its concerns. However, we believe scoring facilities on measures for which they treat a very small number of patients (*i.e.,* fewer than 11 qualifying patients) may raise greater concerns than reallocating measure weights, because the effect of a single outlier on facility measure scores increases as the patient census decreases. Therefore, while some small facilities may benefit from receiving a score based on performance for their small patient population, others may receive far lower measure scores that are not reflective of the quality of care provided to all patients at the facility. We therefore believe it is most appropriate to continue reallocating measure weights across the measures for which a facility is eligible to receive a score if a facility is not eligible to receive a score on one or more measures.

For these reasons, we are finalizing the weighting for the Clinical Measure Domain as proposed for the PY 2019 ESRD QIP.

ii. Weighting the Total Performance Score

We continue to believe that while the reporting measures are valuable, the clinical measures evaluate actual patient care and therefore justify a higher combined weight (78 FR 72217). We did not propose to change our policy, finalized in the CY 2015 ESRD PPS final rule (79 FR 66219), under which clinical measures will be weighted as finalized for the Clinical Domain score, and the Clinical Domain score will comprise 90 percent of a facility's TPS, with the reporting measures weighted equally to form the remaining 10 percent of a facility's TPS. We also did not propose any changes to the policy that facilities must be eligible to receive a score on at least one reporting measure and at least one clinical measure to be eligible to receive a TPS, or the policy that a facility's TPS will be rounded to the nearest integer, with half of an integer being rounded up.

The comments and our responses are set forth below.

Comment: One commenter did not support weighting the Clinical Measure Domain at 90 percent of a facility's TPS and having reporting measures comprise the remaining 10 percent because it does not adequately incentivize reporting for the increasing number of reporting measures in the ESRD QIP. The commenter recommended that CMS weight the clinical and reporting

measures at 80 percent and 20 percent of a facility's TPS, respectively.

Response: We thank the commenter for its suggestion, and agree that reporting is an important component of quality improvement efforts. We also acknowledge that weighting the reporting measures to comprise 10 percent of a facility's TPS results in each individual reporting measure carrying less weight in the facility's overall score; however, we disagree that this allocation does not adequately incentivize the reporting measures. We continue to believe that clinical measures should carry substantially more weight than reporting measures in a facility's TPS because clinical measures score providers and facilities based upon actual outcomes, providing a direct assessment of the quality of care a facility provides, relative to either the facility's past performance or standards of care nationwide. Reporting measures, on the other hand, create an incentive for facilities to monitor significant indicators of health and illness, help facilities become familiar with CMS data systems, and allow the ESRD QIP to collect the robust clinical data needed to establish performance standards for clinical measures. We do not believe that facilities are failing to report data for the ESRD QIP reporting measures based on the fact that their reporting measure scores will have less of an impact on their TPSs than their Clinical Measure Domain scores. For example, for the Anemia Management and Mineral Metabolism reporting measures, the median of national facility performance is 10 points, meaning that the vast majority of facilities are reporting all required data under these measures. We therefore believe the current weighting scheme is appropriate. We will continue to evaluate the appropriateness of this weighting for future years of the ESRD QIP.

For these reasons, we are finalizing the total performance score weighting for the PY 2019 ESRD QIP.

7. Minimum Data for Scoring Measures for the PY 2019 ESRD QIP

Our policy is to score facilities on clinical and reporting measures for which they have a minimum number of qualifying patients during the performance period. With the exception of the Standardized Readmission Ratio, Standardized Transfusion Ratio, and ICH CAHPS clinical measures, a facility must treat at least 11 qualifying cases during the performance period in order to be scored on a clinical or reporting measure. A facility must have at least 11 index discharges to be eligible to receive a score on the SRR clinical measure and 10 patient-years at risk to be eligible to receive a score on the STrR clinical measure. In order to receive a score on the ICH CAHPS clinical measure, a facility must have treated at least 30 survey-eligible patients during the eligibility period and receive 30 completed surveys during the performance period. We did not propose to change these minimum data policies for the measures that we proposed to continue including in the PY 2019 ESRD QIP measure set.

For the proposed Dialysis Adequacy clinical measure, we proposed that facilities with at least 11 qualifying patients will receive a score on the measure. We believe that maintaining a case minimum of 11 for this measure adequately addresses both the privacy and reliability concerns previously discussed in the CY 2013 ESRD PPS final rule (77 FR 67510 through 67512), and aligns with the case minimum policy for the previously finalized clinical process measures.

For the proposed Ultrafiltration Rate and Full-Season Influenza reporting measures, we also proposed that facilities with at least 11 qualifying patients will receive a score on the measure. We believe that setting the case minimum at 11 for these reporting measures strikes the appropriate balance between the need to maximize data collection and the need to not unduly burden or penalize small facilities. We further believe that setting the case minimum at 11 is appropriate because this aligns with case minimum policy for the vast majority of the reporting measures in the ESRD QIP.

Under our current policy, we begin counting the number of months for which a facility is open on the first day of the month after the facility's CCN Open Date. Only facilities with a CCN Open Date before July 1, 2017 would be eligible to be scored on the Anemia Management, Mineral Metabolism, Pain Assessment and Follow-Up, Clinical Depression Screening and Follow-Up reporting measures, and only facilities with a CCN Open Date before January 1, 2017 would be eligible to be scored on the NHSN Bloodstream Infection clinical measure, ICH CAHPS clinical measure, and NHSN Healthcare Personnel (HCP) Influenza Vaccination reporting measure. Consistent with our policy regarding the NHSN HCP Influenza Vaccination reporting measure, we proposed that facilities with a CCN Open Date after January 1, 2017 would not be eligible to receive a score on the Full-Season Influenza Vaccination reporting measure because these facilities might have difficulty reporting the data by the proposed reporting deadline of May 15, 2017. We further proposed that, consistent with our CCN Open Date policy for other reporting measures, facilities with a CCN Open Date after July 1, 2017, would not be eligible to receive a score on the Ultrafiltration Rate reporting measure because of the difficulties these facilities may face in meeting the requirements of this measure due to the short period of time left in the performance period. Table 26 displays the proposed patient minimum requirements for each of the measures, as well as the proposed CCN Open Dates after which a facility would not be eligible to receive a score on a reporting measure.

TABLE 26—PROPOSED MINIMUM DATA REQUIREMENTS FOR THE PY 2019 ESRD QIP

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Dialysis Adequacy (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.
Vascular Access Type: Catheter (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Vascular Access Type: Fistula (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.
NHSN Bloodstream Infection (Clinical)	11 qualifying patients	Before January 1, 2017	11–25 qualifying patients.
SRR (Clinical)	11 index discharges	N/A	11–41 index discharges.
STrR (Clinical)	10 patient-years at risk	N/A	10–21 patient-years at risk.

TABLE 26—PROPOSED MINIMUM DATA REQUIREMENTS FOR THE PY 2019 ESRD QIP—Continued

Measure	Minimum data requirements	CCN open date	Small facility adjuster
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	Before January 1, 2017	N/A.
Anemia Management (Reporting)	11 qualifying patients	Before July 1, 2017	N/A.
Mineral Metabolism (Reporting)	11 qualifying patients	Before July 1, 2017	N/A.
Depression Screening and Follow-Up (Reporting).	11 qualifying patients	Before July 1, 2017	N/A.
Pain Assessment and Follow-Up (Reporting).	11 qualifying patients	Before July 1, 2017	N/A.
NHSN HCP Influenza Vaccination (Reporting).	N/A	Before January 1, 2017	N/A.
Ultrafiltration Rate (Reporting)	11 qualifying patients	Before July 1, 2017	N/A.
Full-Season Influenza Vaccination (Reporting).	11 qualifying patients	Before January 1, 2017	N/A.

The comments and our responses are set forth below.

Comment: One commenter requested that CMS revert to the minimum data proposal for the Anemia Management and Mineral Metabolism reporting measure as finalized in the PY 2016 ESRD PPS final rule.

Response: In the CY 2015 ESRD PPS final rule with comment period, we finalized our policy to set the case minimum for the Anemia Management and Mineral Metabolism reporting measures at 11 qualifying patients for PY 2017 and future payment years (79 FR 66185). We continue to believe that this case minimum strikes the appropriate balance between the need to maximize data collection and the need to not unduly penalize small facilities that are unable, for legitimate reasons, to meet the reporting requirements previously established for these measures (78 FR 72197 through 72199 and 72220 through 72221).

Comment: One commenter acknowledged that the small number of pediatric ESRD patients often results in facilities not being scored on the pediatric dialysis adequacy measures, but noted that CMS' minimum sample size for the measures is based on CMS' policies related to compliance with the HIPAA Privacy Regulations, not quality performance policies. Another commenter opposed the minimum data requirements for the proposed Dialysis Adequacy Measure because, if the individual measures are combined, facilities previously excluded for having too few patients, may now be included in the measure, potentially causing privacy concerns.

Response: Given the ESRD QIP's potential to encourage quality improvement, our goal is to ensure the full participation of as many facilities as possible in the program. While patient privacy concerns are one of a number of considerations we take into account when establishing case minimums for measures, we believe that ensuring measure and measure score reliability is vital for quality improvement. As a general principle, reliability improves with increasing case size; that is, the reliability of a measure or score describes numerically to what extent that measure or score assesses the actual differences in performance among facilities as opposed to the random variation within facilities (77 FR 67510). Our current policy is that a facility must treat at least 11 qualifying patients during the performance period in order to be scored on a clinical measure (77 FR 67510 through 67511). This case minimum of 11 patients ensures that the Dialysis Adequacy clinical measure scores meet our standards for measure reliability. We do not believe a case minimum of 11 for the Dialysis Adequacy clinical measure raises privacy concerns, because we do not intend to publish age- or modality-specific performance rates at this time. As a result, patients treated at a facility should not be individually identifiable within the facility's Dialysis Adequacy clinical measure score reflecting the care provided to all eligible patients at the facility.

Comment: One commenter recommended that CMS grant facilities that receive a CCN during the performance period a grace period of 90 days following receipt of their CCN before being scored based on data reported to CROWNWeb because the CROWNWeb registration process is difficult for new users and may therefore hinder new facilities' ability to submit data by the deadlines established for the ESRD QIP. In the alternative, the commenter recommended granting new facilities an additional 90 days to submit their first three months' data in CROWNWeb in order to ensure the submitted data is correct.

Response: We appreciate the commenter's concerns about the difficulties new facilities face when meeting the requirements of the ESRD QIP. It is because of these concerns that facilities with CCN open dates after July 1 of the performance period are excluded from the reporting measures and are therefore not eligible to receive a TPS for that program year. However, we disagree that new facilities should be given an additional ''grace period'' of 90 days for data submission to CROWNWeb. First, we note that facilities can gain access to CROWNWeb in order to submit patient data in advance of receiving their CCN, and we encourage new facilities to contact their ESRD Network regarding this process while awaiting receipt of their CCN. In addition, the CROWNWeb system is not configured to allow ad hoc extensions or suspensions of clinical months for individual facilities. We also believe that financial incentives provide the strongest incentive to improve the quality of care provided to patients with ESRD. For these reasons, we do not believe providing new facilities with an extension of time to begin submitting data to CROWNWeb is appropriate at this time.

Comment: One commenter recommended that CMS determine facility eligibility for a given measure based on patient census for both clinical

and reporting measures on a monthly basis rather than for the entire performance period.

Response: We believe that determining facility eligibility on a monthly basis rather than using the current methodology would have two negative impacts on the ESRD QIP and, by extension, the ESRD population. First, determining eligibility on a monthly basis would likely reduce the number of facilities eligible to receive a score on a measure by excluding facilities that would receive scores under the current methodology. For example, monthly eligibility determinations would systematically exclude months in which facilities do not treat enough eligible patients, instead of basing eligibility for the measure on the total number of eligible patients treated throughout the performance period. Monthly eligibility determinations would also effectively exclude all patients treated at a facility during a month in which the facility is not eligible to receive a score from the ESRD QIP, which runs contrary to the ESRD QIP's goal of ensuring quality of care for all ESRD patients. Second, determining facility eligibility on a monthly basis would require extensive and complicated modifications to the current measure scoring methodologies in order to ensure measure and measure score reliability. For example, some clinical measures require multiple months of claims in order to score facility performance on the measure; it is unclear how the commenter's recommended methodology would account for months during that range in which the facility did not treat enough qualifying cases. In addition, for instances where a facility would only be eligible for a number of months during the performance period, as opposed to the entire performance period, the resulting measure score may inaccurately reflect the quality of care provided at the facility. For these reasons, we believe that determining facility eligibility using the entire performance period is the most appropriate policy for the ESRD QIP.

Comment: One commenter recommended that CMS implement a patient-month threshold for facility eligibility for the NHSN BSI clinical measure.

Response: Currently, eligibility for the NHSN BSI clinical measure is determined based on the number of qualifying patients treated during the performance period. We continue to believe this threshold is appropriate for the NHSN BSI clinical measure because it aligns this measure with the remaining clinical measures in the ESRD QIP, and ensures that the measure captures a larger proportion of dialysis patients than it may otherwise capture.

Comment: One commenter supports the proposed minimum data for scoring measures.

Response: We thank the commenter for its support.

Comment: Two commenters recommended that CMS increase the minimum number of cases from 11 to 26 to avoid anomalous results and to align with the policies used by commercial and managed care value-based purchasing programs. One of the commenters noted that these plans rely upon a minimum of 26 cases and recommended that the ESRD QIP align its minimum data requirements with these plans.

Response: We recognize that measures using a case minimum of 11 could potentially be less reliable than measures using a case minimum of 26. However, we continue to believe that it is essential to score facilities with between 11 and 25 qualifying cases on the applicable ESRD QIP measures, because increasing the minimum number of cases to 26 would result in the exclusion of hundreds of facilities from the ESRD QIP. Based on data from CY 2013, applying a 26-patient case minimum to all the PY 2017 clinical measures would result in the exclusion of 562 facilities from the ESRD QIP, or 9.2 percent of facilities nationwide (79 FR 66185). Given the inherent tradeoff between a modest decline in measure reliability and including these facilities in the ESRD QIP, we believe that on balance it is more important to include these facilities. We also note that the ESRD QIP maintains the SFA in order to ensure that any error in measure rates due to a small number of cases will not adversely affect facility payment.

Comment: One commenter supported CMS's decision to exclude facilities with a CCN Open Date after January 1, 2017 for the Full-Season Influenza Vaccination reporting measure.

Response: We thank the commenter for its support. We note that, based on comments received, we have decided not to finalize the Full-Season Influenza Vaccination reporting measure at this time.

Comment: One commenter supported CMS' proposal to exclude facilities with a CCN Open Date after July 1, 2017 from scoring for the Ultrafiltration Rate reporting measure.

Response: We thank the commenter for its support. We note that, based on comments received, we have decided not to finalize the Ultrafiltration Rate reporting measure at this time.

For these reasons, we are finalizing the minimum data policies for PY 2019 as proposed, with the exception of the Ultrafiltration Rate and Full-Season Influenza Vaccination reporting measure minimum data policies, which we are not finalizing at this time.

8. Payment Reductions for the PY 2019 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. We proposed that, for the PY 2019 ESRD QIP, a facility will not receive a payment reduction if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if:

- It performed at the performance standard for each clinical measure; and
- It received the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2017 reporting measures.

We did not propose a policy regarding the inclusion of measures for which we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the performance period in the PY 2019 minimum TPS. We did not propose such a policy because no measures in the proposed PY 2019 measure set meet this criterion. However, we stated that should we choose to adopt a clinical measure in future rulemaking without the baseline data required to calculate a performance standard before the beginning of the performance period, we will propose a criterion accounting for that measure in the minimum TPS for the applicable payment year at that time.

The PY 2017 program is the most recent year for which we will have calculated final measure scores before the beginning of the proposed performance period for PY 2019 (that is, CY 2017). Because we have not yet calculated final measure scores, we are unable to determine the 50th percentile of facility performance on the PY 2017 reporting measures. We will publish that value in the CY 2017 ESRD PPS final rule once we have calculated final measure scores for the PY 2017 program.

Section 1881(h)(3)(A)(ii) of the Act requires that facilities achieving the lowest TPSs receive the largest payment reductions. In the CY 2014 ESRD PPS final rule (78 FR 72223 through 72224), we finalized a payment reduction scale

for PY 2016 and future payment years: for every 10 points a facility falls below the minimum TPS, the facility would receive an additional 0.5 percent reduction on its ESRD PPS payments for PY 2016 and future payment years, with a maximum reduction of 2.0 percent. We did not propose any changes to this policy for the PY 2019 ESRD QIP.

Because we are not yet able to calculate the performance standards for each of the clinical measures, we are also not able to calculate a proposed minimum TPS at this time. We will publish the minimum TPS, based on data from CY 2015 and the first part of CY 2016, in the CY 2017 ESRD PPS final rule.

We sought comments on this proposal. The comments and our responses are set forth below.

Comment: Two commenters supported the proposed payment reductions for the PY 2019 ESRD QIP.

Response: We thank the commenters for their support.

For these reasons, we are finalizing the payment reduction policies for the PY 2019 ESRD QIP as proposed.

I. Future Achievement Threshold Policy under Consideration

Under our current methodology, we set performance standards, achievement thresholds, and benchmarks for the clinical measures at the 50th, 15th, and 90th percentiles, respectively, of national performance on the measure during the baseline period (77 FR 67500 through 67502). As we continue to refine the ESRD QIP's policies, we are evaluating different methods of ensuring that facilities strive for continuous improvement in their delivery of care to patients with ESRD. For future rulemaking, we are considering increasing the achievement threshold from the 15th percentile to the 25th percentile of national performance during the baseline period. We believe this increase in the achievement threshold will add additional incentives for facilities to improve performance, thereby improving patient outcomes and quality of care. We have analyzed the impact of this policy change on facility payment reductions using the same data used to calculate the PY 2018 minimum TPS. The full results of this analysis can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Achievement-Threshold-Analysis-using-PY-2015-Results.pdf.*

We invited comment on this policy that we are considering for adoption in the ESRD QIP in the future. The comments and our responses are set forth below.

Comment: Many commenters expressed significant concerns with the future achievement threshold policy under consideration. Specifically, commenters are concerned that the increasing use of measures outside the dialysis facility's control, combined with a higher achievement threshold, will result in too many facilities being penalized. Additionally, one commenter described a need, within the ESRD community, to redistribute money currently retained by CMS through the PPS bundle and ESRD QIP payment reductions within the ESRD community to ensure that the quality of patient care improves continuously. One commenter also pointed out that there has been consistent improvement in the numerical values associated with the achievement threshold, suggesting that lower performers have plenty of motivation for improvement, argued that the current achievement threshold policy is already driving improvement among dialysis facilities across all measures, and requested that CMS publish the data used in consideration of inviting comment on this potential future policy proposal. One commenter also expressed concerns that with the new standardized ratio measures being included in the QIP, there may be unexpected effects in QIP scoring. Because decisions to admit patients and transfuse them are generally not made by the dialysis facility, the commenter argued, facilities have little ability to drive improvement or to control how their quality efforts affect patient outcomes. The commenter therefore argued that CMS should wait to see how the current QIP scoring affects those facilities before adding additional uncertainty for them by increasing the achievement threshold.

Response: We thank the commenters for sharing their concerns regarding a potential future policy proposal under consideration that would increase the achievement threshold from the 15th percentile to the 25th percentile of national performance during the baseline period. We will take these comments into consideration as we further consider whether to propose to adopt a higher achievement threshold in the future.

J. Monitoring Access to Dialysis Facilities

In the CY 2015 ESRD PPS final rule, we finalized our commitment to conduct a study to determine the impact of adopting the Standardized Readmission Ratio (SRR) and Standardized Transfusion Ratio clinical measures on access to care, and stated that we would make further details about the study and its methodology available to the public for review (79 FR 66189). We stated that we intended to publish the methodology for this study in the second half of the year, and encouraged all interested parties to review this methodology and submit any comments using the process outlined on the Web page.

We received comments on this issue. The comments and our responses are set forth below.

Comment: Many commenters supported CMS's intent to conduct a study on the impact of adopting the SRR and STrR clinical measures on patient access to care. One commenter recommended that CMS also evaluate the combined effects of socioeconomic status and patient demographics to determine if these attributes influence facility performance on those two measures. Several commenters recommended that CMS exclude these measures from the ESRD QIP until the access to care study results have been thoroughly reviewed and analyzed, or at the very least that CMS delay implementation of the measures until the results of the study are available.

Response: We thank the commenters for their support of the upcoming access to care study, and will take their recommendations regarding the structure and content of the study into account as we continue to develop the study methodology. We note, however, that the purpose of this study is to assess the impact of the SRR and STrR clinical measures on access to care for dialysis patients. If these measures are removed from the ESRD QIP or suspended during the access to care study, it would be very difficult for the study to accurately assess their impact on admission practices. Therefore, we believe it is inappropriate to remove or suspend the SRR and STrR clinical measures while the access to care study is ongoing.

Comment: Several commenters supported CMS's efforts to evaluate the impact of the SRR and STrR measures on access to care. Commenters recommended that CMS evaluate the effectiveness of the SRR and STrR measures in measuring the actual care provided in dialysis facilities and commended CMS for allowing stakeholders to comment on the study methodology.

Response: We thank the commenters for their support.

We thank commenters for providing input regarding the Access to Care Study methodology, which we intend to publish prior to the end of CY 2015.

IV. Advancing Health Information Exchange

HHS has a number of initiatives designed to improve health and health care quality through the adoption of health information technology and nationwide health information exchange. As discussed in the August 2013 Statement ''Principles and Strategies for Accelerating Health Information Exchange'' (available at *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*), HHS believes that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to electronic health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. Health information technology (health IT) that facilitates the secure, efficient and effective sharing and use of electronic health-related information when and where it is needed is an important tool for settings across the continuum of care, including ESRD facilities.

The Office of the National Coordinator for Health Information Technology (ONC) has released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (Roadmap)(available at *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*). The Roadmap describes a shared strategy for achieving nationwide interoperability to enable a learning health system by 2024. In the near term, the Roadmap focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use priority data domains to improve health care quality and outcomes by the end of 2017. The Roadmap also identifies four critical pathways that health IT stakeholders should focus on now in order to create a foundation for long-term success: (1) Improve technical standards and implementation guidance for priority data domains and associated elements; (2) rapidly shift and align federal, state, and commercial payment policies from fee-for-service to value-based models to stimulate the demand for interoperability; (3) clarify and align federal and state privacy and security requirements that enable interoperability; and (4) align and promote the use of consistent policies and business practices that support interoperability and address those that impede interoperability, in coordination with stakeholders.

In addition, ONC has released the draft version of the 2016 Interoperability Standards Advisory (available at *https://www.healthit.gov/standards-advisory/2016*), which provides a list of the best available standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these ''best available standards'' into account as they implement interoperable health information exchange across the continuum of care.

We encourage stakeholders to utilize health information exchange and certified health IT to effectively and efficiently help providers improve internal care delivery practices, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures, and improve efficiencies and reduce unnecessary costs. As adoption of certified health IT increases and interoperability standards continue to mature, HHS will seek to reinforce standards through relevant policies and programs.

V. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

B. Requirements in Regulation Text

In sections II.B.1.d.ii, II.B.1.d.iii, II.B.3, and II.B.4 of this final rule, we made changes to regulatory text for the ESRD PPS in CY 2016. However, the changes that are being made do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text, as specified above. However, this final rule does make reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections.

1. ESRD QIP

a. Wage Estimates

In previous rulemaking, we used the mean hourly wage of a registered nurse as the basis of the wage estimates for all collection of information calculations in the ESRD QIP (for example, 77 FR 67521). However, we believe that reporting data for the ESRD QIP measures can be accomplished by other administrative staff within the dialysis facility. The Bureau of Labor Statistics (the Bureau) is ''the principal Federal agency responsible for measuring labor market activity, working conditions, and price changes in the economy.'' [14] Acting as an independent agency, the Bureau provides objective information not only for the government, but also for the public. The Bureau's National Occupational Employment and Wage Estimate describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data.[15] Therefore, we believe it is reasonable assume these individuals would be tasked with submitting measure data to CROWNWeb rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients.[16] The mean hourly wage of a Medical Records and Health Information Technician is $18.68 per hour.[17] Under OMB Circular 76–A, in calculating direct labor, agencies should not only include salaries and wages, but also ''other entitlements'' such as fringe benefits.[18] This Circular provides that the civilian position full fringe benefit cost factor is 36.25 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $25.45 as the basis of the wage estimates for all collection of

[14] *http://www.bls.gov/bls/infohome.htm.*

[15] *http://www.bls/gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[16] *http://www.bls.gov/ooh/healthcare/registered-nurses.htm.*

[17] *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html.*

[18] *http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction.*

information calculations in the ESRD QIP.

We did not receive comments on this proposal, and are therefore finalizing the change in wage estimates as proposed.

b. Changes in Time Required to Submit Data Based on Proposed Reporting Requirements

In previous rulemaking, we estimated that data entry associated with the ESRD QIP took approximately 5 minutes per data element to complete (for example, 77 FR 67521). However, a large number of facilities now submit data using the batch submission process, which allows facilities to submit data extracted from their internal Electronic Health Records (EHRs) directly to CROWNWeb. Because the batch submission process can be automated with very little human intervention, we believe the overall time required to submit measure data using CROWNWeb is substantially less than previously estimated. We are therefore revising our estimate to be 2.5 minutes per data element submitted, a change of −2.5 minutes, which takes into account the small percentage of data that is manually reported, as well as the human interventions required to modify batch submission files such that they meet CROWNWeb's internal data validation requirements.

We received comments on this section. The comments and our responses are set forth below.

Comment: One commenter expressed concern about an under-estimate in the proposed estimated time to complete QIP data submission because they feel it does not properly account for the needs of smaller facilities without data extraction tools. The commenter explained that while larger facilities are able to utilize data extraction tools that minimize the time needed to submit data, smaller facilities without these capabilities must enter this data manually on a monthly basis. The commenter asserted that it takes an estimated 20–30 minutes per patient per month to enter this data for manual entry facilities.

Response: We thank the commenter for sharing their concerns regarding the proposed estimated time to complete QIP data submission. We understand that the amount of time required to enter data for a patient varies among facilities based on a number of factors, including the facility's size, staffing, and access to different technical support tools, and took these concerns into account when estimating the average time needed to complete data entry across all facilities. We also understand that, because this is an estimated time per element across all facilities, some facilities will require more time to complete the required data submission, and others will require less time. However, we believe an estimate of 2.5 minutes per element is appropriate for assessing the impact of ESRD QIP data submission requirements on facilities because it represents an average of the time required across all facilities, and therefore allows us to better assess burden on a national level.

For these reasons, we are finalizing the change in estimated time required to submit data for the ESRD QIP as proposed.

c. Data Validation Requirements for the PY 2018 ESRD QIP

Section III.F.4 in this final rule outlines our data validation proposals for PY 2018. Specifically, we proposed to randomly sample records from 300 facilities as part of our continuing pilot data-validation program. Each sampled facility will be required to produce approximately 10 records, and the sampled facilities will be reimbursed by our validation contractor for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit this data, we estimate that the aggregate cost of the CROWNWeb data validation would be $19,088 (750 hours × $25.45/hour) total or $64 ($19,088/300 facilities) per facility in the sample. The burden associated with these requirements is captured in an information collection request currently available for review and comment, OMB control number 0938–NEW.

Under the proposed continuation of the feasibility study for validating data reported to the NHSN Dialysis Event Module, we proposed to randomly select nine facilities to provide CMS with a quarterly list of all positive blood cultures drawn from their patients during the quarter, including any positive blood cultures collected on the day of, or the day following, a facility patient's admission to a hospital. A CMS contractor will review the lists to determine if dialysis events for the patients in question were accurately reported to the NHSN Dialysis Event Module. If we determine that additional medical records are needed to validate dialysis events, facilities will be required to provide those records within 60 days of a request for this information. We estimate fewer than ten respondents in a 12-month period; therefore, in accordance with the implementing regulations of the PRA at 44 U.S.C. 3502(3)(A)(i), the burden associated with the aforementioned requirements is exempt.

d. Proposed Ultrafiltration Rate Reporting Measure

We proposed to include, beginning with the PY 2019 ESRD QIP, a reporting measure requiring facilities to report in CROWNWeb an ultrafiltration rate at least once per month for each qualifying patient. However, as discussed in section III.H.2.c.i above, and based on comments received, we decided not to finalize the Ultrafiltration Rate reporting measure at this time. Therefore, facilities will not be subject to additional collection of information requirements for this measure.

e. Proposed Full-Season Influenza Vaccination Reporting Measure

In the CY 2016 ESRD PPS proposed rule, we proposed to include, beginning with the PY 2019 ESRD QIP, a measure requiring facilities to report patient influenza vaccination status annually using the CROWNWeb system. However, as discussed in section III.H.2.c.ii above, based on comments received, we decided not to finalize the Full-Season Influenza Vaccination reporting measure at this time. Therefore, facilities will not be subject to additional collection of information requirements for this measure.

VI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory

alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as economically significant); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule is not economically significant within the meaning of section 3(f)(1) of the Executive Order, since it does not meet the $100 million threshold. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations, and the Departments have provided the following assessment of their impact. We solicited comments on the regulatory impact analysis provided.

2. Statement of Need

This rule finalizes a number of routine updates for renal dialysis services and implements several policy changes to the ESRD PPS in CY 2016. The routine updates include: Wage index values, wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Other policy changes include implementation of section 1881(b)(14)(F)(i)(I), as amended by section 217(b)(2) of PAMA, which requires a 1.25 percent decrease to the payment update as discussed in section II.B.2. of this rule, the delay in payment for oral-only drugs under the ESRD PPS until January 1, 2025 as required by section 204 of ABLE, the implementation of a geographic facility adjustment paid to rural facilities, and the updated payment multipliers based upon the regression analysis discussed in section II.B.1.c. of this final rule. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2016.

This rule finalizes requirements for the ESRD QIP, including the adoption of a measure set for the PY 2019 program, as directed by section 1881(h) of the Act. Failure to finalize requirements for the PY 2019 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2018. In addition, finalizing requirements for the PY 2019 ESRD QIP provides facilities with more time to review and fully understand new measures before their implementation in the ESRD QIP.

3. Overall Impact

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately $10 million in payments to ESRD facilities in CY 2016, which includes the amount associated with updates to outlier threshold amounts, updates to the wage index, changes in the CBSA delineations, changes in the labor-related share, update to the payment rate and changes involved with the refinement.

For PY 2018, we anticipate that the new burdens associated with the collection of information requirements will be approximately $19 thousand, totaling an overall impact of approximately $11.8 million as a result of the PY 2018 ESRD QIP.[19] For PY 2019, we estimate that the payment reductions will result in a total impact of approximately $15.5 million across all facilities.

B. Detailed Economic Analysis

1. CY 2016 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2015 to estimated payments in CY 2016. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2015 and CY 2016 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used the June 2015 update of CY 2014 National Claims History file as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2014 claims to 2015 and 2016 using various updates. The updates to the ESRD PPS base rate are described in section II.B.2.d. of this final rule. Table 27 shows the impact of the estimated CY 2016 ESRD payments compared to estimated payments to ESRD facilities in CY 2015.

TABLE 27—IMPACT OF FINAL CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2016 FINAL RULE

[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2016 changes in outlier policy (percent)	Effect of 2016 changes in wage indexes, CBSA designations and labor share (percent)	Effect of 2016 changes in payment rate update (percent)	Effect of 2016 final refinement changes to payment rate (percent)	Effect of total 2016 final changes (refinement and routine updates to the payment rate) (percent)
	A	B	C	D	E	F	G
All Facilities	6,374	44.5	0.0	0.0	0.15	0.0	0.2
Type							
Freestanding	5,919	41.9	0.0	0.0	0.15	0.0	0.2
Hospital based	455	2.7	0.0	0.1	0.16	−0.1	0.2

[19] We note that the aggregate impact of the PY 2018 ESRD QIP was included in the CY 2015 ESRD PPS final rule (79 FR 66256 through 66258). The previously finalized aggregate impact of $11.8 million reflects the PY 2018 estimated payment reductions and the collection of information requirements for the NHSN Healthcare Personnel Influenza Vaccination reporting measure.

TABLE 27—IMPACT OF FINAL CHANGES IN PAYMENTS TO ESRD FACILITIES FOR CY 2016 FINAL RULE—Continued

[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2016 changes in outlier policy (percent)	Effect of 2016 changes in wage indexes, CBSA designations and labor share (percent)	Effect of 2016 changes in payment rate update (percent)	Effect of 2016 final refinement changes to payment rate (percent)	Effect of total 2016 final changes (refinement and routine updates to the payment rate) (percent)
	A	B	C	D	E	F	G
Ownership Type							
Large dialysis organization	4,446	31.5	0.0	−0.1	0.15	0.1	0.2
Regional chain	957	6.8	0.0	0.2	0.15	−0.3	0.1
Independent	594	4.0	0.0	0.1	0.15	−0.1	0.2
Hospital based [1]	377	2.2	0.0	0.0	0.16	0.3	0.4
Geographic Location							
Rural	1,259	6.6	0.0	−1.2	0.15	0.9	−0.1
Urban	5,115	37.9	0.0	0.2	0.15	−0.1	0.2
Census Region							
East North Central	1,049	6.5	0.0	−0.2	0.15	0.2	0.1
East South Central	523	3.3	0.0	−1.2	0.15	0.7	−0.2
Middle Atlantic	687	5.4	0.0	0.8	0.15	−0.3	0.7
Mountain	365	2.2	0.0	−0.3	0.15	−0.1	−0.2
New England	182	1.4	0.0	0.9	0.15	−0.6	0.5
Pacific [2]	778	6.2	0.0	1.7	0.15	−0.8	1.1
Puerto Rico and Virgin Islands	47	0.3	0.0	−3.9	0.15	−0.2	−3.8
South Atlantic	1,414	10.3	0.0	−0.5	0.15	0.3	0.1
West North Central	466	2.3	0.0	−0.8	0.15	0.2	−0.4
West South Central	863	6.5	0.0	−0.8	0.15	0.2	−0.3
Facility Size							
Less than 4,000 treatments [3]	1,416	3.4	0.0	−0.3	0.15	0.4	0.3
4,000 to 9,999 treatments	2,346	12.2	0.0	−0.4	0.15	0.0	−0.1
10,000 or more treatments	2,596	29.0	0.0	0.2	0.15	−0.1	0.3
Unknown	16	0.0	0.0	−0.3	0.14	0.0	−0.1
Percentage of Pediatric Patients							
Less than 2%	6,264	44.1	0.0	0.0	0.15	0.0	0.2
Between 2% and 19%	42	0.4	0.0	0.1	0.15	0.3	0.6
Between 20% and 49%	13	0.0	0.0	−0.1	0.15	0.6	0.7
More than 50%	55	0.1	−0.1	−0.2	0.15	0.6	0.5

[1] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

[2] Includes ESRD facilities located in the states in the Pacific region, including those located in Guam, American Samoa, and the Northern Mariana Islands.

[3] Of the 1,416 ESRD facilities with less than 4,000 treatments, only 387 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these low-volume facilities is a 6.9 percent increase in payments.

Note: Totals do not necessarily equal the sum of rounded parts, as percentages are multiplicative, not additive.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final changes to the outlier payment policy described in section II.B.2.c. of this final rule is shown in column C. For CY 2016, the impact on all ESRD facilities as a result of the changes to the outlier payment policy will be a 0.0 percent increase in estimated payments. Nearly all ESRD facilities are anticipated to experience no effect in their estimated CY 2016 payments as a result of the final outlier policy changes.

Column D shows the effect of the final CY 2016 wage indices, and the final year of the transitions for the implementation of both the new CBSA delineations and the labor-related share. Facilities located in the census region of Puerto Rico and the Virgin Islands would receive a 3.9 percent decrease in estimated payments in CY 2016. Since most of the facilities in this category are located in Puerto Rico, the decrease is primarily due to the change in the labor-related share. The other categories of types of facilities in the impact table show changes in estimated payments ranging from a 1.2 percent decrease to a 1.7 percent increase due to these final updates.

Column E shows the effect of the ESRD PPS payment rate update of 0.15 percent, which reflects the final ESRDB market basket percentage increase factor for CY 2016 of 1.8 percent, the 1.25 percent reduction as required by the section 1881(b)(14)(F)(i)(I) of the Act, and the MFP adjustment of 0.4 percent.

Column F shows the effect of the ESRD PPS refinement as discussed in

section II.B.1. While the overall estimated impact of the refinement is 0.0 percent, the impact by categories ranges from a 0.8 percent decrease to a 0.9 percent increase.

Column G reflects the overall impact (that is, the effects of the final outlier policy changes, the final wage index, the effect of the change in CBSA delineations, the effect of the change in the labor-related share, the effect of the payment rate update, and the effect of the refinement). We expect that overall ESRD facilities will experience a 0.2 percent increase in estimated payments in 2016. ESRD facilities in Puerto Rico and the Virgin Islands are expected to receive a 3.8 percent decrease in their estimated payments in CY 2016. This larger decrease is primarily due to the negative impact of the change in the labor-related share. The other categories of types of facilities in the impact table show impacts ranging from a decrease of 0.4 percent to an increase of 1.1 percent in their 2016 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers, (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2016, we estimate that the final ESRD PPS will have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2016 will be approximately $9.6 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.4 percent in CY 2016.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 0.2 percent overall increase in the final ESRD PPS payment amounts in CY 2016, we estimate that there will be an increase in beneficiary co-insurance payments of 0.2 percent in CY 2016, which translates to approximately $0 million due to rounding.

e. Alternatives Considered

In section II.B.1.c.1. of this final rule, we finalized the updated payment multipliers for five age groups resulting from our regression analysis. In section II.B.2.d., we discuss and finalize a refinement budget-neutrality adjustment to account for the overall effects of the refinement. We are finalizing a 4 percent reduction (that is, a factor of .960319) to the ESRD PPS base rate to account for the additional dollars paid to facilities through the payment adjustments. We indicated that a significant portion of additional impact of the adjusters on the base rate arises from changes in the age adjustments. To mitigate some of the reduction, we considered reducing the number of age categories to three and providing a payment adjustment for only those patients in the youngest (18–44) and oldest (80+) age groups. We did not adopt this approach because while it would reduce the impact of the age adjustments on the base rate, it would also significantly reduce the explanatory power of the system and reduce payments to facilities with patients who are between the ages of 44 through 79, that is, approximately 75 percent of patients.

Also, in section II.B.1.d. of this final rule, we finalized the eligibility criteria for the low-volume payment adjustment by excluding facilities of common ownership that are located within 5 road miles off one another. We considered a geographic proximity criterion of 10 road miles; however, this approach negatively impacted rural facilities which are important to ensure access to essential renal dialysis services.

2. End-Stage Renal Disease Quality Incentive Program

a. Effects of the PY 2019 ESRD QIP

The ESRD QIP provisions are intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries as a result of payment changes under the ESRD PPS. The methodology that we are using to determine a facility's TPS for PY 2019 is described in section III.H.8 of this final rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2019 ESRD QIP would affect the facility's reimbursement rates in CY 2019.

We estimate that, of the total number of dialysis facilities (including those not receiving a TPS), approximately 23 percent or 1,405 of the facilities would likely receive a payment reduction in PY 2019. Facilities that do not receive a TPS are not eligible for a payment reduction.

In conducting our impact assessment, we have assumed that there will be an initial count of 6,264 dialysis facilities paid under the ESRD PPS. Table 28 shows the overall estimated distribution of payment reductions resulting from the PY 2019 ESRD QIP.

TABLE 28—ESTIMATED DISTRIBUTION OF PY 2019 ESRD QIP PAYMENT REDUCTIONS

Percentage reduction	*Frequency*	*Percent*	*Cumulative frequency*	*Cumulative percent*
0	4629	76.72	4629	76.72
0.5	961	15.93	5590	92.64
1	362	6.00	5952	98.64
1.5	65	1.08	6017	99.72
2	17	0.28	6034	100.00

Note: This table excludes 230 facilities that we estimate will not receive a payment reduction because they will not report enough data to receive a Total Performance Score.

To estimate whether or not a facility would receive a payment reduction in PY 2019, we scored each facility on achievement and improvement on several measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Measures used for the simulation are shown in Table 29.

TABLE 29—DATA USED TO ESTIMATE PY 2019 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
Vascular Access Type		
% Fistula	Jan 2013–Dec 2013	Jan 2014–Dec 2014.
% Catheter	Jan 2013–Dec 2013	Jan 2014–Dec 2014.
Dialysis Adequacy	Jan 2013–Dec 2013	Jan 2014–Dec 2014.
Hypercalcemia	Jan 2013–Dec 2013	Jan 2014–Dec 2014.
SRR	Jan 2013–Dec 2013	Jan 2014–Dec 2014.
STrR	Jan 2013–Dec 2013	Jan 2014–Dec 2014.
NHSN BSI	Jan 2014–Dec 2014	Jan 2014–Dec 2014.

Clinical measure topic areas with less than 11 cases for a facility were not included in that facility's Total Performance Score. Each facility's Total Performance Score was compared to the estimated minimum Total Performance Score and the payment reduction table found in section III.H.8 of this final rule. Facility reporting measure scores were estimated using available data from CY 2014. Facilities were required to have a score on at least one clinical and one reporting measure in order to receive a Total Performance Score.

To estimate the total payment reductions in PY 2019 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the one year period between January 2014 and December 2014 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: (Total ESRD payment in January 2014 through December 2014 times the estimated payment reduction percentage). For PY 2014, the total payment reduction for the 1,405 facilities estimated to receive a reduction is approximately $15.5 million ($15,470,309). As a result, we estimate that ESRD facilities will experience an aggregate impact of approximately $15.5 million in PY 2019, as a result of the CY 2016 ESRD PPS final rule with comment period.

Table 30 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2019. The table estimates the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the time periods used for these calculations will differ from those we are proposing to use for the PY 2019 ESRD QIP, the actual impact of the PY 2019 ESRD QIP may vary significantly from the values provided here.

TABLE 30—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES IN PY 2019

	Number of facilities	*Number of treatments 2014 (in millions)*	*Number of facilities with QIP Score*	*Number of facilities expected to receive a payment reduction*	*Payment reduction (percent change in total ESRD payments)*
All Facilities	6,264	40.0	6,023	1,313	−0.15
Facility Type:					
Freestanding	5,812	37.7	5,625	1,215	−0.15
Hospital-based	452	2.3	398	98	−0.23
Ownership Type:					
Large Dialysis	4,380	28.5	4,271	870	−0.13
Regional Chain	926	6.0	891	196	−0.15
Independent	584	3.6	536	165	−0.26
Hospital-based (non-chain)	374	1.9	325	82	−0.24
Facility Size:					
Large Entities	5,306	34.5	5,162	1,066	−0.13
Small Entities[1]	958	5.5	861	247	−0.25
Rural Status:					
1) Yes	1,332	6.5	1,257	194	−0.10
2) No	4,932	33.5	4,766	1,119	−0.16
Census Region:					
Northeast	861	6.2	832	199	−0.17
Midwest	1,490	7.9	1,392	336	−0.17
South	2,744	18.1	2,658	602	−0.15
West	1,112	7.5	1,088	150	−0.09
US Territories[2]	57	0.4	53	26	−0.44
Census Division:					
East North Central	1,036	5.8	966	272	−0.20
East South Central	518	3.0	502	83	−0.11
Middle Atlantic	680	4.9	662	168	−0.18
Mountain	359	2.0	350	48	−0.08
New England	182	1.3	170	31	−0.12
Pacific	760	5.6	745	104	−0.09
South Atlantic	1,386	9.3	1,340	352	−0.18
West North Central	455	2.1	426	64	−0.09
West South Central	841	5.8	816	167	−0.13
US Territories[2]	47	0.3	46	24	−0.48
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,305	3.5	1,202	220	−0.15

TABLE 30—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES IN PY 2019—Continued

	Number of facilities	*Number of treatments 2014 (in millions)*	*Number of facilities with QIP Score*	*Number of facilities expected to receive a payment reduction*	*Payment reduction (percent change in total ESRD payments)*
4,000–9,999 treatments	2,239	10.8	2,207	444	−0.13
Over 10,000 treatments	2,514	25.3	2,484	612	−0.16
Unknown	206	0.3	130	37	−0.29

[1] Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.
[2] Includes Puerto Rico and Virgin Islands.
[3] Based on claims and CROWNWeb data through December 2014.

b. Alternatives Considered

In section III.G.2.c.ii of the CY 2016 ESRD PPS proposed rule, we proposed to adopt the Full-Season Influenza Vaccination reporting measure. Under this proposed measure, data on patient immunization status would be entered into CROWNWeb for each qualifying patient treated at the facility during the performance period. We considered proposing to collect patient immunization data using the CDC's Surveillance for Dialysis Patient Influenza Vaccination module within the NHSN; however, the proposed measure's data sources are administrative claims and ''electronic clinical data'' which the Measure Justification Form explains will be collected via CROWNWeb (MAP #XDEFM). Because the measure specifications reviewed by the Measure Applications Partnership do not include NHSN as a data source for this measure, we decided not to propose to use the NHSN system to collect patient-level influenza vaccination data for this measure at this time.

We ultimately decided to have facilities report data for this measure in CROWNWeb rather than using an alternative data source, for two main reasons. First, the data elements needed for this measure have already been developed in CROWNWeb and will appear in a new release soon. Second, facilities are already familiar with the use and functionality of CROWNWeb because they are using it to report data for other measures in the ESRD QIP, and we believe that familiarity with CROWNWeb will reduce the burden of reporting data for the Full Season Influenza reporting measure.

As discussed in section III.H.2.c.ii above, based on comments received, we decided not to finalize the Full-Season Influenza Vaccination reporting measure at this time.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a±4*), in Table 31 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

TABLE 31—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

ESRD PPS for CY 2016	
Category	Transfers
Annualized Monetized Transfers.	$10 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Transfers
Increased Beneficiary Co-insurance Payments.	$0 million.
From Whom to Whom	Beneficiaries to ESRD providers.
ESRD QIP for PY 2018[20]	
Category	Transfers
Annualized Monetized Transfers.	$−11.8 million.
Category	Costs
Annualized Monetized ESRD Provider Costs.	$19 thousand.
ESRD QIP for PY 2019	
Category	Transfers
Annualized Monetized Transfers.	$−15.5 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs.	N/A.

VII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354) (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 15 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $38.5 million in any 1 year. Individuals and States are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's Web site at *http://www.sba.gov/content/small-business-size-standards* (Kidney Dialysis Centers are listed as 621492 with a size standard of $38.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 15 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 27. Using the definitions in this ownership category, we consider the 594 facilities that are independent and the 377 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by LDOs and regional chains would have total revenues of more than $38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates finalized in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 0.4 percent increase in payments for CY 2016. An

independent facility (as defined by ownership type) is also estimated to receive a 0.2 percent increase in payments for CY 2016.

We estimate that of the 495 ESRD facilities expected to receive a payment reduction in the PY 2019 ESRD QIP, 84 are ESRD small entity facilities. We present these findings in Table 27 (''Estimated Distribution of PY 2019 ESRD QIP Payment Reductions'') and Table 28 (''Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2019'') above. We estimate that the payment reductions will average approximately $7,797 per facility across the 495 facilities receiving a payment reduction, and $7,509 for each small entity facility. Using our estimates of facility performance, we also estimated the impact of payment reductions on ESRD small entity facilities by comparing the total estimated payment reductions for 958 small entity facilities with the aggregate ESRD payments to all small entity facilities. We estimate that there are a total of 958 small entity facilities, and that the aggregate ESRD PPS payments to these facilities would decrease 0.07 percent in PY 2019.

Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities. We solicited comment on the RFA analysis provided.

In addition, section 1102(b) of the Social Security Act (the Act) requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 139 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 139 rural hospital-based dialysis facilities will experience an estimated 1.1 percent decrease in payments. As a result, this final rule is not estimated to have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

VIII. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that is approximately $144 million. This final rule does not include any mandates that will impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $144 million.

IX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

X. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

XI. Files Available to the Public via the Internet

In the past, a majority of the Addenda referred to throughout the preamble of our proposed and final rules were available in the **Federal Register**. However, the Addenda of the annual proposed and final rules will no longer be available in the **Federal Register**. Instead, these Addenda to the annual proposed and final rules will be available only through the Internet on the CMS Web site. The Addenda to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) rules are available at: *http://www.cms.gov/ESRDPayment/PAY/list.asp.* Readers who experience any problems accessing any of the Addenda to the proposed and final rules of the ESRD PPS that are posted on the CMS Web site identified above should contact Michelle Cruse at 410–786–7540.

List of Subjects in 42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 1. The authority citation for part 413 is revised to read as follows:

Authority: 42 U.S.C. 1302; 42 U.S.C. 1395d(d); 42 U.S.C. 1395f(b); 42 U.S.C. 1395g; 42 U.S.C. 1395l(a), (i), and (n); 42 U.S.C. 1395x(v); 42 U.S.C. 1395hh; 42 U.S.C. 1395rr; 42 U.S.C. 1395tt; 42 U.S.C. 1395ww; sec. 124 of Pub. L. 106–113, 113 Stat. 1501A–332; sec. 3201 of Pub. L. 112–96, 126 Stat. 156; sec. 632 of Pub. L. 112–240, 126 Stat. 2354; sec. 217 of Pub. L. 113–93, 129 Stat. 1040; and sec. 204 of Pub. L. 113–295, 128 Stat. 4010.

■ 2. Section 413.174 is amended by revising paragraph (f)(6) to read as follows:

§ 413.174 Prospective rates for hospital based and independent ESRD facilities.

* * * * *

(f) * * *

(6) Effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided.

■ 3. Section 413.232 is amended by—

■ a. Revising paragraph (c)(2).

■ b. Removing paragraph (d).

■ c. Redesignating paragraphs (e), (f), (g), and (h) as paragraphs (d), (e), (f), and (g) respectively.

■ d. Revising newly redesignated paragraph (e).

■ e. In newly redesignated paragraph (g) introductory text, the reference ''paragraph (f)'' is removed and the reference ''paragraph (e)'' is added in its place.

■ f. In newly redesignated paragraph (g)(1), the reference ''paragraph (f)'' is removed and the reference ''paragraph (e)'' is added in its place.

The revision reads as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(c) * * *

(2) Five (5) miles or less from the ESRD facility in question.

* * * * *

(e) Except as provided in paragraph (f) of this section, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor that the facility meets all the criteria established in this section, except that, for calendar year 2012, the attestation must be provided by January 3, 2012, for calendar year 2015, the attestation must be provided by December 31, 2014, and for calendar year 2016, the attestation must be provided by December 31, 2015.

* * * * *

■ 4. Add § 413.233 to read as follows:

§ 413.233 Rural facility adjustment.

CMS adjusts the base rate for facilities in rural areas, as defined in § 413.231(b)(2).

■ 5. Add § 413.234 to read as follows:

§ 413.234. Drug designation process.

(a) *Definitions.* For purposes of this section, the following definitions apply:

ESRD PPS functional category. A distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

New injectable or intravenous product. An injectable or intravenous product that is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, assigned a Healthcare Common Procedure Coding System code, and designated by CMS as a renal dialysis service under § 413.171.

Oral-only drug. A drug or biological with no injectable equivalent or other form of administration other than an oral form.

(b) *Drug designation process.* Effective January 1, 2016, new injectable or intravenous products are included in the ESRD PPS bundled payment using the following drug designation process:

(1) If the new injectable or intravenous product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or intravenous product is considered included in the ESRD PPS bundled payment and no separate payment is available.

(2) If the new injectable or intravenous product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or intravenous product is not considered included in the ESRD PPS bundled payment and the following steps occur:

(i) An existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or intravenous product is used to treat or manage;

(ii) The new injectable or intravenous product is paid for using the transitional drug add-on payment adjustment described in paragraph (c) of this section; and

(iii) The new injectable or intravenous product is added to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

(c) *Transitional drug add-on payment adjustment.* (1) A new injectable or intravenous product that is not considered included in the ESRD PPS base rate is paid for using a transitional drug add-on payment adjustment, which is based on pricing methodologies under section 1847A of the Social Security Act.

(2) The transitional drug add-on payment adjustment is paid until sufficient claims data for rate setting analysis for the new injectable or intravenous product is available, but not for less than two years.

(3) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or intravenous product in the ESRD PPS bundled payment.

(d) *Oral-only drug determination.* An oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration.

■ 6. Section 413.237 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 413.237 Outliers.

(a) * * *

(1) * * *

(iv) Renal dialysis services drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including ESRD-related oral-only drugs effective January 1, 2025.

* * * * *

Dated: October 26, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: October 27, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–27928 Filed 10–29–15; 4:15 pm]

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Part IV

Environmental Protection Agency

40 CFR Part 180
Chlorpyrifos; Tolerance Revocations; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0653; FRL–9935–92]

Chlorpyrifos; Tolerance Revocations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On August 10, 2015, the U.S. Court of Appeals for the Ninth Circuit ordered EPA to respond to an administrative Petition to revoke all tolerances for the insecticide chlorpyrifos by October 31, 2015, by either denying the Petition or issuing a proposed or final tolerance revocation. At this time, the agency is unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard of section 408(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Accordingly, EPA is proposing to revoke all tolerances for chlorpyrifos. EPA is specifically soliciting comment on whether there is an interest in retaining any individual tolerances, or group of tolerances, and whether information exists to demonstrate that such tolerance(s) meet(s) the FFDCA section 408(b) safety standard. EPA encourages interested parties to comment on the tolerance revocations proposed in this document and on the proposed time frame for tolerance revocation. Issues not raised during the comment period may not be raised as objections to the final rule, or in any other challenge to the final rule.

DATES: Comments must be received on or before January 5, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2015–0653 by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Dana Friedman, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave NW., Washington, DC 20460–0001; telephone number: (703) 347–8827; email address: *friedman.dana@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

C. What can I do if I wish the Agency to maintain a tolerance that the Agency proposes to revoke?

This proposed rule provides a comment period of 60 days for any interested person to submit comments on the agency's proposal. EPA will issue a final rule after considering the comments that are submitted. Comments should be limited only to the pesticide and tolerances subject to this proposal.

EPA's finding that it cannot determine if aggregate exposure from all existing uses of chlorpyrifos are safe, does not necessarily mean that no individual tolerance or group of tolerances could meet the FFDCA 408(b)(2) safety standard and be maintained. EPA's risk assessment supporting this proposed rule indicates that the primary source of risk comes from chlorpyrifos and chlorpyrifos oxon in drinking water in highly vulnerable watersheds (generally small watersheds where the land is agricultural and could be treated with chlorpyrifos (*i.e.,* heavily cropped areas)). However, as explained in this proposed rule, some uses of chlorpyrifos do not by themselves present risks of concern from either food or drinking water and are only a concern when aggregated with all exposures to chlorpyrifos. EPA therefore invites comments that address whether some tolerances or groups of tolerances can be retained. In that regard, in addition to information related to the safety of such tolerances, use site specific information pertaining to the pests targeted by chlorpyrifos, and the alternatives to chlorpyrifos for these pests, may help to inform the agency's final decision if EPA is able to conclude that some tolerances may be retained under the FFDCA safety standard. In addition, if EPA receives information that would allow it to better refine the location of at risk watersheds and protect such watersheds through appropriate product labeling restrictions, it is possible EPA could conclude that such mitigation would eliminate the need for some or all of the proposed tolerance revocations. It is important to stress, however, that because the FFDCA is a safety standard, EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe.

After consideration of comments, EPA will issue a final regulation determining whether revocation of some or all of the tolerances is appropriate under section 408(b)(2). Such regulation will be subject to objections pursuant to section 408(g) (21 U.S.C. 346a(g)) and 40 CFR part 178.

In addition to submitting comments in response to this proposal, you may also submit an objection at the time of the final rule. If you anticipate that you may wish to file objections to the final rule, you must raise those issues in your comments on this proposal. EPA received numerous comments on its

December 2014 Revised Human Health Risk Assessment (RHHRA) (Ref. 1) related to the scientific bases underlying this proposed rule. In light of the U.S Court of Appeals for the Ninth Circuit's August 10, 2015 order in *Pesticide Action Network North America (PANNA)* v. *EPA,* No. 14–72794 (*PANNA*), compelling EPA to take this action by October 31, 2015, EPA has not addressed these prior comments in this proposed rule. Persons wishing to have EPA consider previously submitted comments on the RHHRA in connection with this proposal should submit a comment indicating that intention and identifying their earlier comments on the RHHRA. EPA will treat as waived any issue not raised or referenced in comments submitted on this proposal. Similarly, if you fail to file an objection to the final rule within the time period specified, you will have waived the right to raise any issues resolved in the final rule. After the specified time, issues resolved in the final rule cannot be raised again in any subsequent proceedings on this rule making.

II. Background

A. What action is the Agency taking?

EPA is proposing to revoke all tolerances for residues of the insecticide chlorpyrifos as contained in 40 CFR 180.342. This includes tolerances for residues of chlorpyrifos on specific food commodities (180.342(a)(1)); on all food commodities treated in food handling and food service establishments in accordance with prescribed conditions (180.342(a)(2) and(a)(3)); and on specific commodities when used under regional registrations (180.342(c)).

The agency is proposing to revoke all of these tolerances because EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe.

EPA's full risk conclusions supporting this proposal are set forth in the 2014 RHHRA for chlorpyrifos that EPA issued for public comment. That document, supporting materials, and the public comments on those documents are available in the chlorpyrifos registration review docket, EPA–HQ–OPP–2008–0850. While EPA's assessment indicates that contributions to dietary exposures to chlorpyrifos from food and residential exposures are safe, when those exposures are combined with estimated exposures from drinking water, as required by the FFDCA, EPA has determined that safe levels of chlorpyrifos in the diet may be exceeded for people whose drinking water is derived from certain vulnerable watersheds throughout the United States. This primarily includes those populations consuming drinking water from small water systems in heavily cropped areas where chlorpyrifos may be used widely.

B. What is the Agency's authority for taking this action?

EPA is taking this action, pursuant to the authority in FFDCA sections 408(b)(1)(A), 408(b)(2)(A), and 408(d)(4)(A)(ii). 21 U.S.C. 346a(b)(1)(A), (b)(2)(A), (d)(4)(A)(ii).

III. Statutory and Regulatory Background

A ''tolerance'' represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications of tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore ''adulterated'' under FFDCA section 402(a), 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce, 21 U.S.C. 331(a). For a food-use pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under FIFRA, 7 U.S.C. 136a(a); 40 CFR 152.112(g). Food-use pesticides not registered in the United States must have tolerances in order for commodities treated with those pesticides to be imported into the United States.

Section 408(d) of the FFDCA, 21 U.S.C. 346a(d), authorizes EPA to revoke tolerances in response to administrative petitions submitted by any person. Because EPA is unable to determine at this time that aggregate exposures to chlorpyrifos are safe, EPA is proposing to revoke these tolerances in response to a Petition from PANNA and the Natural Resources Defense Council (NRDC) to revoke all chlorpyrifos tolerances (Ref. 2). The timing of this proposal is the result of the August 10, 2015 order in the PANNA decision to respond to that petition by October 31, 2015. This proposal also implements the agency findings made during the registration review process required by section 3(g) of FIFRA (7 U.S.C. 136(a)(g)) which EPA is conducting in parallel with its petition response. That process requires EPA to re-evaluate existing pesticides every 15 years to determine whether such pesticides meet the FIFRA registration standard set forth in FIFRA section 3(c)(5), 7 U.S.C. 136a(c)(5). In part, that standard requires EPA to ensure that dietary risks from the pesticide meet the FFDCA section 408 safety standard. Section 408 directs that EPA may establish or leave in effect a tolerance for pesticide only if it finds that the tolerance is safe, and EPA must revoke or modify tolerances determined to be unsafe. FFDCA 408(b)(2)(A)(i) (21 U.S.C. 346a(b)(2)(A)(i)). Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and all non-occupational exposures (*e.g.* in residential settings), but does not include occupational exposures to workers (*i.e.,* occupational).

Risks to infants and children are given special consideration. Specifically, pursuant to section 408(b)(2)(C), EPA must assess the risk of the pesticide chemical based on available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity.

(21 U.S.C. 346a(b)(2)(C)(i)(II) and (III)).

This provision further directs that ''in the case of threshold effects, . . . an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.'' (21 U.S.C. 346a(b)(2)(C)). EPA is permitted to ''use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.'' (21 U.S.C. 346a(b)(2)(C)). Due to Congress's focus on both pre- and post-natal toxicity, EPA has interpreted this additional safety factor as pertaining to risks to infants and children that arise due to pre-natal exposure as well as to exposure during childhood years. For

convenience sake, the legal requirements regarding the additional safety margin for infants and children in section 408(b)(2)(C) are referred to throughout this proposed rule as the ''FQPA safety factor for the protection of infants and children'' or simply the ''FQPA safety factor.''

IV. Chlorpyrifos Background, Regulatory History, and Litigation

Chlorpyrifos (0,0-diethyl-0-3,5,6-trichloro-2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate (OP) insecticide that has been registered for use in the United States since 1965. Currently registered use sites include a large variety of food crops (including fruit and nut trees, many types of fruits and vegetables, and grain crops), and non-food use settings (*e.g.,* golf course turf, industrial sites, greenhouse and nursery production, sod farms, and wood products). Public health uses include aerial and ground-based fogger mosquito adulticide treatments, roach bait products and individual fire ant mound treatments. In 2000, the chlorpyrifos registrants reached an agreement with EPA to voluntarily cancel all residential use products except those registered for ant and roach baits in child-resistant packaging and fire ant mound treatments.

In 2006, EPA completed FIFRA section 4 reregistration and FFDCA tolerance reassessment for chlorpyrifos and the OP class of pesticides. Given ongoing scientific developments in the study of the OPs generally, EPA chose to prioritize the FIFRA section 3(g) registration review (the next round of re-evaluation following reregistration) of chlorpyrifos and the OP class. The registration review of chlorpyrifos and the OPs has presented EPA with numerous novel scientific issues that have been the subject of multiple FIFRA Scientific Advisory Panel (SAP) meetings since the completion of reregistration that have resulted in significant developments in the conduct of EPA's risk assessments generally, and, more specifically, in the study of chlorpyrifos's effects. These SAP meetings included review of new worker and non-occupational exposure methods, experimental toxicology and epidemiology, risk assessment approaches for semi-volatile pesticides and the evaluation of a chlorpyrifos-specific pharmacokinetic-pharmacodynamic (PBPK–PD) model.

A. Registration Review

In 2011, in connection with FIFRA registration review, EPA issued its Preliminary Human Health Risk Assessment (PHHRA) (Ref. 3) for chlorpyrifos that evaluated exposures from food, drinking water, other non-occupational sources, and occupational risk (such as risks to farmworkers applying chlorpyrifos and working in treated fields). At the time of the PHHRA, EPA had not yet performed an integrated weight of evidence analysis on the lines of evidence related to the potential for neurodevelopmental effects. The PHHRA indicated that for food alone, the acute and chronic dietary risk estimates for all populations assessed were below the level of concern. The residue of concern in treated drinking water is the chlorpyrifos oxon because chlorpyrifos transforms to the more toxic chlorpyrifos oxon in treated drinking water (*e.g.* chlorination). For drinking water alone, EPA had a concern for infant exposures to the chlorpyrifos oxon.

In December 2014, EPA completed the RHHRA for registration review (Ref. 1). The RHHRA represents a highly sophisticated assessment of hazard and exposure to chlorpyrifos and its oxon. The dietary risk assessment in the RHHRA provides the scientific support for this proposed rule. The approach EPA used for the chlorpyrifos dietary assessment and for this proposed rule can be described as follows: EPA conducted dietary exposure modeling using the Dietary Exposure Evaluation Model (DEEM) and the Calendex models (Ref. 4) to develop a probabilistic evaluation of human dietary consumption. Most of the pesticide food residue values used in those models were based upon U.S. Department of Agriculture's (USDA) Pesticide Data Program (PDP) monitoring data. Percent crop treated and empirical food processing factors were used where available. EPA then utilized a PBPK–PD model to calculate both acute (24 hour) and steady state (21 days (*i.e.,* the approximate time to reach steady state for most OPs)) points of departure (PoD) dose levels that represent the minimum amount of chlorpyrifos that presents a risk concern. (OPs exhibit a phenomenon known as steady state AChE inhibition. After repeated dosing at the same dose level, the degree of inhibition comes into equilibrium with the production of new, uninhibited enzyme. OP AChE studies of 2–3 weeks generally show the same degree of inhibition as those of longer duration (*i.e.,* up to 2 years of exposure). Therefore, a steady state assessment based on 21 days of exposure may be conducted in place of the traditional chronic assessment).

For chlorpyrifos, the risk of concern is 10% acetylcholinesterase inhibition (AChE) in red blood cells (RBC)—a precursor for adverse neurological symptoms—for both acute and steady state exposure durations. The PBPK–PD PoD predictions for each human lifestage exposure route and pathway were modeled separately (*e.g.,* for residential exposure *i.e.* dermal, inhalation and incidental oral calculations). PoDs are divided by the total uncertainty factors (which are used to account for potential differences in sensitivities within populations or extrapolations from test results in animals to effects on humans) to derive a population adjusted dose (PAD). There are potential risks of concern when the estimated dietary exposures exceed 100% of the PAD. For the food intake portion of the dietary assessment, the only potential residue of concern is chlorpyrifos (the oxon metabolite is not an expected residue on foods). EPA incorporated total uncertainty factors of 100X for adult females (a 10X FQPA safety factor and another 10X intra-species extrapolation factor since the PBPK–PD model does not include a component that specifically models pregnant women) and 40X for the other relevant populations (a 10X FQPA safety factor and another 4X intra-species data derived extrapolation factor) using the PBPK–PD model to account for potential metabolic and physiological differences between populations. The chlorpyrifos exposure values resulting from dietary modeling are then compared to the PAD to determine the portion of the ''risk cup'' that is taken up by exposures from food. In the case of chlorpyrifos, the RHHRA concluded that food and non-occupational exposures by themselves take up only a small portion of the risk cup and are therefore not a risk concern when considered in isolation.

For the drinking water portion of the dietary assessment, the chlorpyrifos oxon, which is more toxic than chlorpyrifos, is the residue of concern assumed to occur in drinking water. Based on available information regarding the potential effects of certain water treatments (*e.g.,* chlorination appears to hasten transformation of chlorpyrifos to chlorpyrifos oxon), EPA believes it is appropriate to assume that all chlorpyrifos in water is converted to chlorpyrifos oxon upon treatment. The chlorpyrifos oxon total uncertainty factors are 100X for adult females (10X FQPA safety factor and 10X intra-species extrapolation factor to account for potential differences between populations) and 50X for the other

relevant populations (10X FQPA safety factor and 5X intra-species data derived extrapolation factor) using the PBPK–PD model to account for potential metabolic and physiological differences between populations. See Unit VI.5 for how the intra-species factors for chlorpyrifos and chlorpyrifos oxon were derived. After considering food and residential contributions to the risk cup, EPA determined that drinking water concentrations to chlorpyrifos oxon greater than 3.9 ppb for a 21-day average would exceed EPA's Drinking Water Level of Comparison (DWLOC) and present a risk of concern. EPA's water exposure assessment indicated that multiple labeled use scenarios for chlorpyrifos exceed the DWLOC and therefore present a risk concern. On January 14 2015, EPA published a **Federal Register** Notice seeking public comment on the RHHRA.

EPA's drinking water analysis in the RHHRA also showed that the DWLOC exceedances are not expected to be uniformly distributed across the country. As a result, EPA began to conduct further analysis to look at the spatial distribution of Estimated Drinking Water Concentrations (EDWCs) at more refined geographic levels. This exercise demonstrated that chlorpyrifos applications will result in variable drinking water exposures that are highly localized and that the highest exposures generally occur in small watersheds where there is a high percent cropped area on which chlorpyrifos use could occur. Accordingly, following the development of the RHHRA in December 2014, EPA has continued working to develop a more refined assessment to examine EDWCs on a regional and/or watershed scale to pinpoint community drinking water systems where exposure to chlorpyrifos oxon as a result of chlorpyrifos applications may pose an exposure concern. At this time this more refined drinking water assessment that will allow EPA to better identify where at-risk watersheds are located throughout the country is not completed. Thus, we are not currently able to determine with any great specificity which uses in which areas of the country do or do not present a risk concern. EPA intends to update this action, as warranted, with any significant refinements to its drinking water assessment, and intends, to the extent practicable, to provide the public an opportunity to comment on the refined drinking water assessment prior to a final rule.

B. PANNA±NRDC Petition and Associated Litigation

In September 2007, PANNA and NRDC submitted to EPA a Petition seeking revocation of all chlorpyrifos tolerances and cancellation of all FIFRA registrations of products containing chlorpyrifos. In connection with both EPA's response to the Petition and the FIFRA registration review of chlorpyrifos, EPA has taken most of the complex and novel science questions raised in the Petition to the SAP for review and EPA has developed numerous new methodologies (including approaches to address pesticide drift, volatility, and the integration of experimental toxicology and epidemiology) to consider these issues.

While EPA agreed that these new methodologies were necessary to properly evaluate PANNA and NRDC's (Petitioners') claims, Petitioners have been dissatisfied with the pace of EPA's response efforts and have sued EPA in federal court on three separate occasions to compel a prompt response to the Petition. Although EPA has to date addressed 7 of the 10 claims asserted in the Petition by either issuing a preliminary denial or approving label mitigation to address the claim, on June 10, 2015, in the *PANNA* decision, the U.S. Court of Appeals for the Ninth Circuit signaled its intent to order EPA to complete its response to the Petition and directed EPA to inform the court how—and by when—EPA intended to respond. On June 30, 2015, EPA informed the court that, based on the results of its drinking water assessment, EPA intended to propose by April 15, 2016, the revocation of all chlorpyrifos tolerances in the absence of pesticide label mitigation that ensures that drinking water exposures will be safe. EPA proposed this time frame in part to accommodate the completion of a refined drinking water assessment that might allow EPA to identify high risk areas of the country where additional label mitigation could be put in place to address drinking water concerns. On August 10, 2015, the court rejected EPA's time line and issued a mandamus order directing EPA to ''issue either a proposed or final revocation rule or a full and final response to the administrative Petition by October 31, 2015.'' As a result of this order, EPA is issuing this proposed rule in advance of completing its refined drinking water assessment. In addition, EPA has had insufficient time to address comments received on the RHHRA. As a result, EPA may update this action with new or modified analyses as EPA completes additional work after this proposal. For any significant new or modified analyses, to the extent practicable, EPA intends to provide the public an opportunity to comment on that work prior to issuing a final rule.

V. EPA's Approach to Dietary Risk Assessment

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. A short summary is provided below to aid the reader. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, refer to References 5 and 6 respectively. To assess the risk of a pesticide tolerance, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and duration of exposure to the pesticide. The risk assessment process involves four distinct steps: (1) Identification of the toxicological hazards posed by a pesticide; (2) determination of the exposure ''level of concern'' for humans; (3) estimation of human exposure; and (4) characterization of human risk based on comparison of human exposure to the level of concern.

A. Hazard Identification and Selection of Toxicological Endpoint

Any risk assessment begins with an evaluation of a chemical's inherent properties, and whether those properties have the potential to cause adverse effects (*i.e.,* a hazard identification). EPA then evaluates the hazards to determine the most sensitive and appropriate adverse effect of concern, based on factors such as the effect's relevance to humans and the likely routes of exposure.

Once a pesticide's potential hazards are identified, EPA determines a toxicological level of concern for evaluating the risk posed by human exposure to the pesticide. In this step of the risk assessment process, EPA essentially evaluates the levels of exposure to the pesticide at which effects might occur. An important aspect of this determination is assessing the relationship between exposure (dose) and response (often referred to as the dose-response analysis). In evaluating a chemical's dietary risks, EPA uses a reference dose (RfD) approach, which first involves establishing a PoD—or the value from a dose-response curve that is at the low end of the observable data and that is the toxic dose that serves as the starting point in extrapolating a risk to the human population. In typical risk assessments, PoDs are derived directly

from laboratory animal studies, and then EPA extrapolates to potential effects on humans and human populations by applying both inter and intra-species uncertainty factors. Traditionally, EPA has used a 10X factor to address each of these uncertainties. In the case of chlorpyrifos and its oxon, however, EPA has used PBPK–PD modeling to estimate PoDs for all age groups using Data-Derived Extrapolation Factors (DDEF) rather than default uncertainty factors to address intraspecies extrapolation for some groups (Ref. 1). The PBPK–PD model accounts for PK (pharmacokinetic) and PD (pharmacodynamic) characteristics to derive age, duration, and route specific PoDs. Specifically, the following characteristics have been evaluated: exposure (acute, 21-day (steady state); routes of exposure (dermal, oral, inhalation); body weights which vary by lifestage; exposure duration (hours per day, days per week); and exposure frequency (*e.g.,* eating and drinking events per day). While the current PBPK–PD model accounts for age-related growth from infancy to adulthood by using polynomial equations to describe tissue volumes and blood flows as a function of age, the model does not include any descriptions on physiological, anatomical, and biochemical changes associated with pregnancy. Due to the uncertainty in extrapolating the current model predictions among women who may be pregnant, the agency is applying the standard 10X intra-species extrapolation factor for women of childbearing age.

Although the PBPK–PD model's use of data-derived extrapolation factors renders unnecessary the use of traditional inter- and intra- species uncertainty factors for evaluating most populations, as required by FFDCA section 408(b)(2)(C), EPA must also address the need for an additional safety factor to protect infants and children. That provision requires EPA to retain an additional 10-fold margin of safety unless EPA concludes, based on reliable data, that a different safety factor will be safe for infants and children. The PoDs calculated by the PBPK–PD model are then divided by the uncertainty factors to derive a PAD. There are potential risks of concern when the estimated dietary exposure exceeds 100% of the PAD.

B. Estimating Human Exposure Levels

Pursuant to section 408(b) of the FFDCA, EPA evaluated dietary risks for chlorpyrifos based on ''aggregate exposure'' to chlorpyrifos. By ''aggregate exposure,'' EPA is referring to exposure to chlorpyrifos residues by multiple pathways of exposure. EPA uses available data, together with assumptions designed to be protective of public health, and standard analytical methods to produce separate estimates of exposure for a highly exposed subgroup of the general population, for each potential pathway and route of exposure. For both acute and steady state risks, EPA then calculates potential aggregate exposure and risk by using probabilistic techniques to combine distributions of potential exposures in the population for each route or pathway. (Probabilistic analysis is used to predict the frequency with which variations of a given event will occur. By taking into account the actual distribution of possible consumption and pesticide residue values, probabilistic analysis for pesticide exposure assessments ''provides more accurate information on the range and probability of possible exposure and their associated risk values.'' (Ref. 7). In capsule, a probabilistic pesticide exposure analysis constructs a distribution of potential exposures based on data on consumption patterns and residue levels and provides a ranking of the probability that each potential exposure will occur. People consume differing amounts of the same foods, including none at all, and a food will contain differing amounts of a pesticide residue, including none at all). For dietary analyses, the relevant sources of potential exposure to chlorpyrifos are from the ingestion of residues in food and drinking water. EPA uses a combination of monitoring data and predictive models to evaluate environmental exposure of humans to chlorpyrifos.

1. *Exposure from food.* Acute and steady state dietary (food only) exposure analyses for chlorpyrifos were conducted using the Dietary Exposure Evaluation Model (DEEM) and Calendex software with the Food Commodity Intake Database (FCID). The DEEM–FCID model uses 2003–2008 food consumption data from the USDA National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). These current analyses reflect the latest available consumption data as well as more recent food monitoring and percent crop treated data. Both the acute and steady state dietary exposure analyses are highly refined. The large majority of food residues used were based upon USDA's PDP monitoring data except in a few instances where no appropriate PDP data were available. In those cases, field trial data or tolerance level residues were assumed.

DEEM–FCID also compares exposure estimates to appropriate RfD or PAD values to estimate risk. EPA uses these models to estimate exposure for the general U.S. population as well as subpopulations based on age, sex, ethnicity, and region. For its chlorpyrifos assessment, EPA used DEEM–FCID to calculate risk estimates based on a probabilistic distribution that combines the full range of residue values for each food with the full range of data on individual consumption amounts to create a distribution of exposure and risk levels. More specifically, DEEM–FCID creates this distribution by calculating an exposure value for each reported day of consumption per person (''person/day'') in the food survey, assuming that all foods potentially bearing the pesticide residue contain such residue at the chosen value. The exposure amounts for the thousands of person/days in the food survey are then collected in a frequency distribution.

The probabilistic technique that DEEM–FCID uses to combine differing levels of consumption and residues involves the following steps:

(1) identification of any food(s) that could possibly bear the residue in question for each person/day in the USDA food survey;

(2) calculation of an exposure level for each of the thousands of person/days in the USDA food survey database, based on the foods identified in Step #1 by randomly selecting residue values for the foods from the residue database;

(3) repetition of Step #2 one thousand times for each person/day; and

(4) collection of all of the hundreds of thousands of potential exposures estimated in Steps # 2 and 3 in a frequency distribution.

The resulting probabilistic assessment presents a range of exposure/risk estimates that can be compared to appropriate PADs to determine the safety of food exposures.

2. Exposure from water. EPA may use field monitoring data and/or simulation water exposure models to generate pesticide exposure estimates in drinking water. Monitoring and modeling are both important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of the specific agricultural or residential pesticide practices in specific locations, under the environmental conditions associated with a sampling design (*i.e.,* the

locations of sampling, the times of the year samples were taken, and the frequency by which samples were collected). Further, monitoring data can reflect the actual use of a pesticide rather than the label rates. Although monitoring data can provide a direct measure of the concentration of a pesticide in water, it generally does not provide a reliable basis for estimating spatial and temporal variability in exposures because sampling may not occur in areas with the highest pesticide use, and/or when the pesticides are being used and/or at an appropriate sampling frequency to detect high concentrations of a pesticide that occur over the period of a day to several days.

Because of the limitations in most monitoring studies, EPA's standard approach is to use water exposure models as the primary means to estimate pesticide exposure levels in drinking water. EPA's computer models use detailed information on soil properties, crop characteristics, and weather patterns to estimate exposure in vulnerable locations where the pesticide could be used according to its label. (Ref. 8). These models calculate estimated water concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment at these vulnerable locations. The modeling provides an estimate of pesticide concentrations in ground and surface water. Depending on the modeling algorithm (*e.g.,* surface water modeling scenarios), daily concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide.

As discussed in Unit VI.B. in greater detail, EPA relied on models developed for estimating exposure in both surface water and ground water. A detailed description of the models routinely used for exposure assessment is available from the EPA Office of Pesticide Programs (OPP) Water Models Web site: *http://www.epa.gov/oppefed1/models/water/.* The Surface Water Concentration Calculator provides a means for EPA to estimate daily pesticide concentrations in surface water sources of drinking water (a reservoir) using local soil, site, hydrology, and weather characteristics along with pesticide applications and agricultural management practices, and pesticide environmental fate and transport properties. EPA also considers percent cropped area (PCA) factors which take into account the potential extent of cropped areas that could be treated with pesticides in a particular area.

In modeling potential surface water concentrations, EPA attempts to model areas of the country that are highly vulnerable to surface water contamination rather than simply model ''typical'' concentrations occurring across the nation. Consequently, EPA models exposures occurring in small watersheds in different growing areas throughout the country over a 30-year period. The scenarios are designed to capture residue levels in vulnerable drinking water sources and are adjusted by PCA factors. The PCA is calculated from satellite derived land cover data to account for the area of watershed that is cropped.

EPA believes these assessments are likely reflective of a subset of the watersheds across the country that are used for drinking water supply, representing a drinking water source generally considered to be more vulnerable to frequent high concentrations of pesticides than most locations. For this reason, in its evaluation of chlorpyrifos, EPA has also begun to refine its assessment to evaluate drinking water risk at a regional and drinking water intake scale. While it is currently challenging to assess exposure on a local scale due to the unavailability of data and wide range of characteristics (*i.e.,* environmental factors such as soil, weather, etc. or others (*e.g.,* drinking water treatment process)) that affect the vulnerability of a given community drinking water system to chlorpyrifos oxon contamination, EPA developed a method to examine the potential geospatial concentration differences using specific examples for two Hydrological Unit Code (HUC) 2 Regions—HUC 2 Region 17: Pacific Northwest and HUC 2 Region 3: South Atlantic-Gulf, in order to identify use patterns in those regions that may result in EDWCs that exceed the DWLOC on a regional basis. There are 21 HUC 2 regions with 18 in the conterminous United States. These areas contain either the drainage area of a major river, or a combined drainage of a series of rivers. The average size is 177,560 square miles. Additional information can be found at *https://water.usgs.gov/GIS/huc.html.* The analysis used a number of modeling scenarios to represent all potential chlorpyrifos agricultural use sites. This analysis showed an overlap of potential chlorpyrifos use sites that may result in an exceedance of the DWLOC with watersheds that supply source water for community drinking water systems. In addition, this analysis shows that exposure is not uniform within a HUC 2 Region and that some watersheds present risk concerns while others do not. In general, the refined analysis confirms that smaller watersheds with high percent cropped areas are much more vulnerable than large watersheds. When this assessment is complete (*i.e.,* when EPA has completed this analysis for the rest of the country), it may provide EPA with a basis for tailoring its drinking water risk mitigation efforts through pesticide product labeling rather than revoking tolerances nationwide. Because of the *PANNA* decision on August 10, 2015 compelling EPA to respond to the PANNA–NRDC Petition by October 31, 2015, EPA has not been able to complete its refined drinking water assessment for chlorpyrifos in advance of this proposed rule. As a result, this proposal relies only on the results of the national screen that do not provide a basis for more tailored risk mitigation. EPA is continuing to conduct its regional and water-intake level assessment and intends to update this action if warranted with the results of that assessment when it is completed. For any significant new or modified drinking water analyses, to the extent practicable, EPA intends to provide the public an opportunity to comment on the work prior to issuing a final rule.

3. *Residential and Other Non-Occupational Exposures.* EPA's ''residential'' assessments actually examine exposure to pesticides in both residential and other non-occupational settings (*e.g.,* homes, parks, schools, athletic fields or any other areas frequented by the general public). All residential uses of chlorpyrifos except ant and roach baits (in child resistant packaging) and fire ant mound treatments were voluntary cancelled by registrants in 2000. As such, the use of the term ''residential'' throughout this document does not connote there are residential uses, rather it is used interchangeable with ''non-occupational'' exposures. Exposures to pesticides may occur to persons who apply pesticides or to persons who enter areas previously treated with pesticides. Such exposures may occur through oral, inhalation, or dermal routes. For chlorpyrifos, the uses that could result in non-occupational exposures are the public health uses as an aerial and ground-based ultra-low volume (ULV) fogger for adult mosquito control, the fire ant mound treatments, the use in ant and roach bait stations, and foliar use on golf course turfgrass.

Non-occupational assessments are conducted through examination of significant exposure scenarios (*e.g.,*

children playing on treated lawns or homeowners spraying their gardens) using a combination of generic and pesticide-specific data. To regularize this process, OPP has prepared Standard Operating Procedures (SOPs) for conducting ''residential'' assessments on a wide array of scenarios that are intended to address all major possible means by which individuals could be exposed to pesticides in a non-occupational environment (*e.g.* homes, schools, parks, athletic fields, or other publicly accessible locations). The SOPs identify relevant generic data and construct algorithms for calculating exposure amounts using these generic data in combination with pesticide-specific information. The generic data generally involve survey data on behavior patterns (*e.g.,* activities conducted on turf and time spent on these activities), unit exposure, and transfer coefficient data to evaluate the transfer of pesticide to humans from a treated surface.

Typically, non-occupational risks are quantified by comparison of estimates of exposure to toxicological PoDs for each route of exposure as selected from laboratory animal studies. In the case of chlorpyrifos, the PBPK–PD model was used to derive age-, duration-, and route-specific human equivalent doses. Separate PoDs were calculated for residential exposures by varying inputs on types of exposures and populations exposed. Residential risk estimates, or margins of exposure (MOEs) were calculated with use of the scenario- and lifestage-specific PoDs by comparison to exposure estimates (doses) quantified with use of standard occupational and residential exposure assessment methodologies.

C. Selection of Acute and Steady State Dietary Exposure Level of Concern

Because probabilistic assessments generally present a realistic range of residue values to which the population may be exposed, EPA's starting point for estimating exposure and risk for its aggregate risk assessments is the 99.9th percentile of the population under evaluation. When using a probabilistic method of estimating acute and steady state dietary exposure, EPA typically assumes that, when the 99.9th percentile of exposure is equal to or less than the PAD, the level of concern has not been exceeded and dietary exposures are safe.

D. Aggregating Exposures and Deriving a Risk Estimate

In an aggregate risk assessment, pesticide exposures from relevant sources (*i.e.,* food, drinking water and non-occupational uses) are added together and compared to quantitative estimates of hazard (*e.g.,* PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, both the route and duration of exposures are considered. For chlorpyrifos, EPA has considered aggregate exposures and risks from combined food, drinking water, and non-occupational exposures. Residues in food consist of parent compound chlorpyrifos only, while concentrations in water are assumed to consist of chlorpyrifos oxon only. The acute aggregate assessment includes only food and drinking water while the steady state aggregate assessment includes exposures from food, drinking water, and non-occupational scenarios. Typically, in aggregate assessments, total dietary exposure (food and drinking water combined) are derived by incorporating both food residues and EDWCs in the dietary exposure model. In the chlorpyrifos RHHRA, only food exposures were derived from the dietary model. For drinking water exposure and risk, a DWLOC approach was used to calculate the amount of exposure which could occur without exceeding the risk level of concern (*i.e.,* the available space in the total aggregate risk cup for exposures to chlorpyrifos oxon in drinking water after accounting for exposures to parent chlorpyrifos from food and non-occupational scenarios). The calculated DWLOCs were then compared to the EDWCs of oxon modeled under a variety of conditions. When the EDWC is less than the DWLOC, there are no risk concerns for exposures to the pesticide in drinking water which also indicates aggregate exposures are not of concern. Conversely, when the EDWC is greater than the DWLOC, then potential risks of concern are identified.

VI. Aggregate Risk Assessment and Conclusions Regarding Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA's assessment of exposures and risks associated with chlorpyrifos use follows.

A. Hazard Identification and Endpoint Selection

This unit summarizes EPA's review of relevant data for extrapolating risk and its integrative analysis using multiple lines of evidence from experimental toxicology and epidemiology with respect to AChE/ChE inhibition (acetylcholinesterase/cholinesterase) and neurodevelopmental outcomes. This section also describes EPA's use of a robust PBPK–PD model for deriving PoDs and refined intra-species factors. Finally, this unit provides the quantitative results of the end-point selection process, including EPA's evaluation and application of the FQPA safety factor.

1. Background. Mode of action (MOA) and adverse outcome pathways (AOPs) provide important concepts and organizing tools for risk assessment. MOAs/AOPs describe a set of measureable key events that make up the biological processes leading to an adverse outcome and the causal linkages between such events. An AOP further defines the initial step in the process as the molecular initiating event. Fundamentally, MOA and AOP are different terms for basically the same concept.

It is well established that AChE inhibition is the mode of action/adverse outcome pathway (MOA/AOP) for the cholinergic toxicity of OP pesticides, including chlorpyrifos. AChE breaks down acetylcholine (ACh), a compound that assists in transmitting signals through the nervous system. When AChE is inhibited at nerve endings by chlorpyrifos or another AChE inhibiting pesticide, the inhibition prevents the ACh from being degraded and results in prolonged stimulation of nerves and muscles. If a person has enough exposure to chlorpyrifos for poisoning to occur the physical signs and symptoms include headache, nausea, dizziness, blurred vision, slurred speech, excessive perspiration, salivation, vomiting, diarrhea, and muscle twitching. Severe exposure to chlorpyrifos can lead to convulsions, loss of bladder and bowel control, coma, difficulty breathing, pulmonary edema, muscle paralysis, and death from respiratory failure. Because AChE inhibition is the initiating event for this MOA/AOP, using AChE inhibition as a regulatory endpoint is protective of downstream cholinergic effects. Moreover, given the sensitivity of AChE inhibition data for OPs, using AChE inhibition to establish a regulatory point of departure has historically been considered to be protective of other potential toxicities. EPA uses a value of 10% AChE inhibition as a point of departure in its regulation of AChE inhibiting pesticides, including chlorpyrifos. EPA's analyses have demonstrated that 10% is a level that can be reliably measured in the majority of animal toxicity studies; is generally at or near the limit of sensitivity for discerning a statistically significant decrease in AChE activity across the brain compartment; and is a response

level close to the background AChE level.

Newer lines of research on chlorpyrifos, notably epidemiological studies, have raised some uncertainty about EPA's historical risk assessment approach for chlorpyrifos with regard to the potential for neurodevelopmental effects that may arise from prenatal exposure to chlorpyrifos. This research is summarized in Unit VI.A.6.iii.

2. Summary of data evaluated for deriving PoDs. Chlorpyrifos and its oxon are widely studied and thus have an extensive database of scientific studies. Included in the database are: Studies developed by registrants pursuant to EPA guidelines, special studies conducted by the registrants, and studies in the public literature. These studies reflect different levels of biological organization (*e.g.,* metabolism, MOA/AOP, *in vitro* and *in vivo* experimental toxicology, biomonitoring, and epidemiology), various species (mouse, rabbit, dog, non-rodent, and human) and address multiple lifestages (fetal, postnatal, pregnant, and non-pregnant adult). The metabolism and pharmacokinetic (PK) profile of chlorpyrifos and its oxon have been extensively studied in *in vitro* systems, *in vivo* laboratory animals, as well as humans. Chlorpyrifos is bioactivated to the more toxic and potent AChE inhibitor, the oxon form. 3,5,6-trichloro-2-pyridinol (TCPy) is the major excreted metabolite and is used as the biomarker in PK, biomonitoring, and epidemiology studies. Diethylphosphate (DEP) is another metabolite often used in biomonitoring studies, but since it is produced by a number of OPs, DEP is not a specific marker for chlorpyrifos.

Summarized below are key findings from experimental toxicology studies on AChE inhibition as presented in detail in the June 2011 PHHRA and the December 2014 RHHRA. Readers should refer to those documents (Refs. 3 and 1) and their appendices in the public docket for this proposed rule for a complete summary of EPA's data review. Chlorpyrifos has also been evaluated for other adverse outcomes such as reproductive toxicity, developmental toxicity, cancer, genotoxicity, dermal toxicity, inhalation toxicity, and immunotoxicity. These adverse outcomes are less sensitive (*i.e.,* are likely to occur at higher doses) than AChE inhibition and neurodevelopmental effects, which form the scientific foundation of this proposed rule, and are thus not discussed in detail here. Concerns for neurodevelopmental effects provide the basis for retention of the FQPA safety factor and are summarized in Unit VI.A.6.

AChE inhibition remains the most robust quantitative dose response data for chlorpyrifos and thus continues to be the critical effect for the quantitative risk assessment. This approach is consistent with the advice EPA received from the FIFRA SAP in both 2008 and 2012 (Refs. 9 and 10) when EPA sought input specifically on the agency's approach to evaluating the toxicity of chlorpyrifos. EPA has conducted benchmark dose (BMD) analysis of numerous studies using empirical approaches previously endorsed by the FIFRA SAP (Ref. 11) and consistent with the 2006 OP cumulative risk assessment (Ref. 12) and other single chemical OP risk assessments. Details on AChE studies and related analyses can be found in Appendix 1 of the PHHRA (Ref. 3).

There are many chlorpyrifos studies evaluating AChE inhibition in red blood cell (RBC) or brain in multiple lifestages (gestational, fetal, post-natal, and non-pregnant adult), multiple species (rat, mouse, rabbit, dog, human), methods of oral administration (oral gavage with corn oil, dietary, gavage via milk), and routes of exposure (oral, dermal, inhalation via vapor, and via aerosol). In addition, chlorpyrifos is unique in the availability of ChE data from peripheral tissues in some studies (*e.g.,* heart, lung, liver). There are also literature studies comparing the *in vitro* ChE response to a variety of tissues (Ref. 13) which show similar sensitivity and intrinsic activity. Across the database, brain AChE tends to be less sensitive than RBC AChE or peripheral ChE. In oral studies, RBC AChE inhibition is generally similar in response to peripheral tissues (*e.g.,* liver, heart, and lung). Thus, the *in vitro* data and oral studies combined support the continued use of RBC AChE inhibition as the critical effect for quantitative dose-response assessment.

As with many OPs, female rats tend to be more sensitive than males to these AChE effects. For chlorpyrifos, there are data from multiple studies which provide robust RBC AChE data in pregnant, lactating, and non-pregnant female rats from oral exposure (*e.g.,* DNT, reproductive, and subchronic rats), respectively. The BMD_{10}/$BMDL_{10}$ values from these studies range from 0.05/0.04 to 0.15/0.09 mg/kg/day. (BMD_{10} is the estimated dose to yield 10% inhibition in RBC AChE inhibition compared to controls or background levels. The $BMDL_{10}$ is the lower 95% confidence limit on the BMD_{10}). Studies are available in juvenile pups which show age-dependent differences, particularly following acute exposures, in sensitivity to chlorpyrifos and its oxon. As discussed above, this sensitivity is not derived from differences in the AChE enzyme itself but instead is derived largely from the immature metabolic clearance capacity in the juveniles.

Multiple route-specific laboratory animal studies for the dermal and inhalation routes are available. Dermal AChE data are available from a 21-day study and 4-day probe study (Ref. 14) in rats which together establish a No Observed Adverse Effect Level (NOAEL) of 5 mg/kg/day and a Lowest Observed Adverse Effect Level (LOAEL) of 10 mg/kg/day. Two subchronic inhalation toxicity studies (Refs. 15, 16, and 17) in the rat are available using vapor phase chlorpyrifos which show no ChE effects up to a concentration of 20.6 ppb (287 $\mu g/m^3$ or 0.082 mg/kg/day). Multiple acute inhalation studies are also available. In a special acute inhalation study, female rats were exposed by nose only (mass median aerodynamic diameter/geometric standard deviation was 1.9/1.51, respectively) to atmospheric concentrations of up to 53.9 mg/m^3 of particulate chlorpyrifos for six hours and allowed an additional 72 hours to recover (Refs. 18 and 19). Consistent and significant lung ChE inhibition were noted at the lowest concentration tested of 3.7 mg/m^3, which is a LOAEL. RBC and brain ChE inhibition were noted at $\geq$ 12.9 mg/m^3 and 53.9 mg/m^3, respectively, indicating they are less sensitive than lung and plasma ChE inhibition following acute inhalation exposures.

Since the 2011 PHHRA, two acute inhalation studies on the saturated vapor have been performed on the parent chlorpyrifos and chlorpyrifos oxon (Refs. 20 and 21). In these studies, female rats were exposed by nose only to a saturated vapor of chlorpyrifos or its oxon for 6 hours to a time-weighted concentration of 17.7 ppb (0.254 mg/m^3) (Ref. 20) or 2.58 ppb (35.3 $\mu g/m^3$) (Ref. 21), respectively. There were no statistically-significant decreases in ChE activity in the RBC, lung, brain, or plasma tissues. These acute studies along with the subchronic inhalation studies with vapor phase chlorpyrifos support a conclusion that acute exposure to the saturated vapor of chlorpyrifos or its oxon do not result in hazard due to AChE inhibition.

3. Durations of Exposure, Critical Windows of Exposure, & Temporality of Effects Relevant for AChE Inhibition. In risk assessment, exposure is evaluated in conjunction with the toxicology profile. More specifically, a variety of pharmacokinetic and pharmacodynamic factors are considered. In the case of

chlorpyrifos, exposure can occur from a single exposure (*e.g.,* eating a meal) or from repeated days of exposure (*e.g.,* worker, residential).

With respect to AChE inhibition, these effects can occur from a single exposure or from repeated exposures. Generally, for OPs, repeated exposures result in more AChE inhibition at a given administered dose compared to acute studies. Moreover, AChE inhibition in repeated dosing guideline toxicology studies with OPs show a consistent pattern of inhibition reaching steady state at or around 2–3 weeks of exposure in adult laboratory animals (Ref. 22). This pattern is observed with repeated dosing and is a result of an equilibrium between the amount of AChE inhibition and the production of new enzyme. As such, AChE studies of 2–3 weeks generally show the same degree of inhibition with those of longer duration (*i.e.,* up to 2 years of exposure). Thus, for most of the single chemical human health risk assessments for the OPs, EPA is focusing on the critical duration range from a single day up to 21 days (*i.e.,* the approximate time to reach steady state for most OPs). As described below, PoDs for various lifestages, routes, and scenarios have been derived at the acute and steady state durations. For this proposed rule, PoDs for various lifestages, routes, and scenarios have been derived at the acute and steady state durations.

4. Use of the Chlorpyrifos PBPK±PD Model to Establish PoDs. As described in detail in EPA's 2006 document entitled, ''Approaches for the Application of Physiologically Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment,'' (Ref. 23) PBPK modelling is a scientifically sound and robust approach to estimating the internal dose of a chemical at a target site and as a means to evaluate and describe the uncertainty in risk assessments. PBPK models consist of a series of mathematical representations of biological tissues and physiological processes in the body that simulate the absorption, distribution, metabolism, and excretion (ADME) of chemicals that enter the body. Examples of PBPK model applications in risk assessments include interspecies extrapolation, intra-species extrapolation, route-to-route extrapolation, estimation of response from varying exposure conditions, and high-to-low dose extrapolation. PBPK models can be used in conjunction with an exposure assessment to improve the quantitative characterization of the dose-response relationship and the overall risk assessment. These models can also be used to evaluate the relationship between an applied dose and biomonitoring data.

For a full discussion of the development and evaluation of the chlorpyrifos PBPK–PD model, please refer to the December 2014 RHHRA (Ref. 1) in the public docket for this rule.

As discussed above, in typical risk assessments, PoDs are derived directly from laboratory animal studies and inter- and intra-species extrapolation is accomplished by use of ''default''10X factors. In the case of chlorpyrifos and its oxon, EPA is using a PBPK–PD model as a data-derived approach to estimate PoDs. This model was originally developed by Timchalk and coworkers in 2002 (Refs. 24 and 25), partially funded by EPA Star Grants, and most recently supported by Dow AgroSciences. The PBPK–PD model for chlorpyrifos has been heavily peer reviewed through numerous scientific publications and a review by the FIFRA SAP (Ref. 26). All model code for the PBPK–PD model are provided in the public docket for the chlorpyrifos risk assessment. Developers of the chlorpyrifos PBPK–PD model sponsored a third-party quality assurance assessment to verify model parameter values and their respective sources. EPA has also done a quality assurance assessment of the model for human health risk assessment applications. (Ref. 27).

The chlorpyrifos PBPK–PD model includes the description of a molecular initiating event in the cholinergic toxicity MOA/AOP: AChE inhibition. Thus, the PBPK–PD model can be used to predict the dose metrics associated with cholinergic toxicity following chlorpyrifos exposure, *i.e.,* RBC and brain AChE inhibition. The model also predicts levels of chlorpyrifos, its oxon, and TCPy in various tissues, such as plasma and urine. Age-specific parameters are incorporated allowing for lifestage-specific evaluations from infant through adulthood. The model can be run in two modes: deterministic and variation. In the deterministic mode, the output accounts for human specific metabolism and physiology, thus obviating the need for the inter-species extrapolation factor for all age groups. In variation mode, distributions for 16 parameters, which are critical for determining human variations in RBC AChE inhibition, are incorporated and thus the output accounts for intra-species extrapolation for infants, toddler, youths, and non-pregnant adults. The approach to intra-species extrapolation is described in Unit VI.A.5.

With respect to AChE inhibition, as noted, EPA typically uses a 10% response level in its human health risk assessments. This response level is consistent with EPA's 2006 OP cumulative risk assessment (Ref. 12) and other single chemical OP risk assessments. As such, EPA has used the PBPK–PD model to estimate exposure levels resulting in 10% RBC AChE inhibition following single day (acute; 24 hours) and 21-day exposures for a variety of exposure scenarios. The model accounts for PK and PD characteristics to derive age, duration, and route specific PoDs (see Table 1 below). Separate PoDs have been calculated for dietary (food, drinking water) and residential exposures by varying inputs on types of exposures and populations exposed. Specifically, the following characteristics have been evaluated: Duration (acute, 21-day (steady state)); route (dermal, oral, inhalation); body weights which vary by lifestage; exposure duration (hours per day, days per week); and exposure frequency (events per day (eating, drinking)).

For each exposure scenario, the appropriate body weight for each age group or sex was modeled as identified from the Exposure Factors Handbook (Ref. 28) for residential exposures and from the NHANES/WWEIA Survey (Ref. 29) for dietary exposures.

EPA evaluated the following scenarios: dietary exposure to the oxon exposures via drinking water (24-hour and 21-day exposures for infants, children, youths, and female adults); exposure to chlorpyrifos exposures via food (24-hour and 21-day exposures for infants, children, youths, and female adults); 21-day residential exposures to chlorpyrifos via skin for children, youths, and female adults; 21-day residential exposures to chlorpyrifos via hand-to-mouth ingestion for children 1–2 years old; and 21-day residential exposures to chlorpyrifos via inhalation for children 1–2 years old and female adults.

For all residential dermal exposures to chlorpyrifos, EPA set the fraction of skin in contact with chlorpyrifos to 50% and assumed a daily shower (*i.e.,* washing off the chlorpyrifos) following chlorpyrifos exposure. All residential exposures were set to be continuous for 21 days. For residential exposures via golfing on treated turf, the daily exposure time is assumed to be 4 hours/day; for residential exposures via contact with turf following public health mosquitocide application, the daily exposure duration is assumed to be 1.5 hours. For residential inhalation exposures following public health

mosquitocide application, the exposure duration was set to 1 hour per day for 21 days. The exposure times selected are based on those recommended in the 2012 *Standard Operating Procedures for Residential Pesticide Exposure Assessment* (2012 Residential SOPs). (Ref. 30).

Summarized in Table 1 are the PBPK–PD model results used to estimate exposure levels resulting in 10% RBC AChE inhibition for each evaluated population.

TABLE 1—CHLORPYRIFOS PBPK MODELED DOSES (PODS) CORRESPONDING TO 10% RBC ACHE INHIBITION [1]

RA Type	Exposure pathway (all chlorpyrifos unless noted)	Infants (< 1 yr old)		Young Children (1–2 years old)		Children (Residential: 6–11 years old; Dietary: 6–12 years old)		Youths (Residential: 11–16 years old; Dietary: 13–19 years old)		Females (13–49 years old)	
		Acute	Steady state (21 day)	Acute	Steady state (21 day)	Acute	Steady state (21 day)	Acute	Steady state (21 day)	Acute	Steady state (21 day)
Dietary	Drinking Water (oxon conc, ppb).	1,183	217	3,004	548	7,700	1,358	4,988	878	5,285	932
	Food (ug/kg/day)	600	103	581	99	530	90	475	80	467	78
Residential (Golfers).	Dermal (ug/kg/day)						25,150		16,370		14,250
Residential (Mosquitocide Application).	Dermal (ug/kg/day)				187,000						38,650
	Oral (ug/kg/day)				101						
	Inhalation (concn. in air mg/m3).				2.37						6.15

[1] Empty cells are not populated because these exposure scenarios are either not relevant for the age group (*e.g.,* infants or 1–2 year olds golfing), or do not represent the most health protective life stage for assessment of a particular exposure scenario as recommended in the 2012 SOPs (*e.g.,* for mosquitocide exposure assessment, children 1 to < 2 years old result in a more protective assessment than infants).

5. Use of the Chlorpyrifos PBPK±PD Model to Extrapolate from Animals to Humans (Inter-species) and Among the Human Population (Intra-species). Once EPA determines the appropriate toxicological PoDs (Table 1), it then applies appropriate uncertainty factors or DDEFs to account for inter-species and intra-species variation, and to address the requirements of section 408(b)(2)(C) regarding the need for an additional margin of safety for infants and children. Specifically, the modeled doses (PoDs) in this table are divided by appropriate factors to establish PADs that are used for regulatory purposes. The PADs are presented in Unit VI.B.2.ii and iii, Tables 2 and 3.

In a typical risk assessment, the agency uses PoDs derived from laboratory animal studies. For these typical assessments, the agency must then extrapolate from animals to humans which is generally performed with a 10X inter-species factor. As noted above in Unit V.A., the output of the chlorpyrifos PBPK–PD model accounts for human specific metabolism and physiology, thus obviating the need for the inter-species extrapolation factor for all age groups.

EPA has, however, calculated a DDEF to address intra-species variation not accounted for in the output of the PBPK–PD model. Consistent with EPA's ''Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation'' (Ref. 31), when calculating a DDEF, EPA compares the administered doses leading to the response level of interest (10% change in RBC AChE inhibition) between a measure of average response and response at the tail of the distribution representing sensitive individuals. Dow AgroSciences has conducted an analysis to derive the oral doses that cause 10% RBC AChE inhibition in both adults and 6-month old infants. (Ref. 1 at 69–70). The ratio of the adult ED_{10} (effective dose) to the infant ED_{10} was then used to derive intraspecies extrapolation factors. In the subsequent Monte Carlo simulations, the target age group is six month old individuals. Based on the 1st percentile of the distributions being used to extrapolate human health, the DDEF for intraspecies extrapolation is 4X for chlorpyrifos and 5X for the oxon (Ref. 32) for all groups except women who are pregnant or may become pregnant.

While the current PBPK–PD model accounts for age-related growth from infancy to adulthood by using polynomial equations to describe tissue volumes and blood flows as a function of age, the model does not include any descriptions on physiological, anatomical and biochemical changes associated with pregnancy. Due to the uncertainty in extrapolating the current model predictions among women who may be pregnant, EPA is applying the standard 10X intra-species extrapolation factor for women of child bearing age.

6. Retention of the statutory 10X FQPA Safety Factor for purposes of this proposed rule for infants, children, youths, and women of childbearing age for all exposure scenarios. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses acceptable risk to humans.

In applying the FQPA safety factor provision, EPA has interpreted the statutory language as imposing a presumption in favor of applying an additional 10X safety factor (Ref. 33). Thus, EPA generally refers to the additional 10X factor as a presumptive or default 10X factor. EPA has also made clear, however, that the presumption can be overcome if reliable data demonstrate that a different factor is safe for infants and children. (Ref. 33). In determining whether a different factor is safe for infants and children, EPA focuses on the three factors listed in section 408(b)(2)(C)—the completeness of the toxicity database, the completeness of the exposure database, and potential pre- and post-natal toxicity.

In examining these factors, EPA strives to make sure that its choice of a safety factor, based on its weight-of-evidence evaluation, does not understate the risk to infants and

children. New lines of research on chlorpyrifos, notably epidemiological studies, have raised some uncertainty about EPA's risk assessment approach for chlorpyrifos with regard to the potential for neurodevelopmental effects that may arise from prenatal exposure to chlorpyrifos. Over the last several years, the agency has taken a stepwise, objective and transparent approach to evaluate, interpret, and characterize the strengths and uncertainties associated with all the lines of scientific information related to the potential for adverse neurodevelopmental effects in infants and children as a result of prenatal exposure to chlorpyrifos. The agency has evaluated multiple lines of evidence with regard to the potential for neurodevelopmental outcomes associated with exposure to chlorpyrifos. These are summarized below; full details of this analysis can be found in the RHHRA. Given the degree of uncertainty EPA has in the human dose-response relationship for neurodevelopmental effects, EPA is retaining the statutory 10X FQPA Safety Factor for purposes of this proposed rule for infants, children (including youths), and women of childbearing age (to address prenatal exposure to the fetus) for all exposure scenarios.

i. Neurodevelopmental outcomes in laboratory animals. There is a considerable and still-growing body of literature on the effects of chlorpyrifos on the developing brain of laboratory animals (rats and mice) indicating that gestational and/or postnatal exposure may cause persistent behavioral effects into adulthood. These data provide support for the susceptibility of the developing mammalian brain to chlorpyrifos exposure. Literature searches have been conducted and periodically updated by EPA to review papers addressing long-term outcomes from developmental exposure. This review has focused on studies in which chlorpyrifos was administered during gestation and/or the pre-weaning period and the offspring are examined at some time after weaning, and on studies using relatively low doses (*e.g.,* 1 mg/kg/day) that would not be expected to produce considerable brain AChE inhibition and resultant cholinergic toxicity.

There are substantial differences in the studies, including critical features of experimental design such as developmental period of exposure, dosing scenarios, testing methods, age at testing, and statistical analyses. Despite these differences, behavioral changes of some sort were reported in most studies. Given the wide array of testing that has been conducted, some variability is not unexpected and in fact, the consistency of finding neurological effects is striking. After presentation of these reviews, FIFRA SAP Panels (Refs. 9 and 10) have agreed that exposure to doses of 1 mg/kg/d and greater, during some developmental period, produce significant and long-term effects on animal behavior.

Many of these studies using various cognitive tests report perturbations of learning and/or memory, even though in a few cases these may be manifested as improved function. Several findings using specific test methods have been replicated across studies and laboratories, increasing confidence in the outcomes. Likewise, alterations in some domains, such as those describing anxiety and social interactions, are not fully consistent, but are still suggestive of long-term impacts on these behaviors. Motor activity measures, on the other hand, produce results as varied as the different measures of assessment. Taken together, these data provide evidence for more global alterations in neurobehavioral function rather than a specific profile of effects.

In these papers, testing was conducted at various times after weaning (adolescents to adults), and there is a presumption that the effects are permanent; however, no study has directly addressed this issue. Dose-response is not always evident, since many studies only use one dose, and of those using two or more doses, there is not always a monotonic response. There are differences in route of administration (oral, subcutaneous) and vehicle (corn oil, DMSO), but the outcomes do not provide obvious differences due to these factors. Likewise, the experimental literature has not consistently shown that any specific developmental period is critical overall to the long-term outcomes. For example, using one specific test cognitive changes were observed following gestational and early postnatal, but not late postnatal, exposures (Refs. 34, 35, 36, and 37). On the other hand, deficits have been reported using a different cognitive test following both gestational and late postnatal exposures (Refs. 38, 39, and 40). Similarly, some changes in anxiety and social behaviors were reported at both gestational and postnatal exposure periods. Unfortunately, no laboratory has provided systematic comparisons across exposure period, dosing regimen, and age of testing; such studies would improve understanding of the impact of these critical factors.

These studies have almost exclusively focused on doses that could produce some degree, however minimal, of AChE inhibition. For example, a number of papers use a dose of 1 mg/kg/d administered 1–4 days after birth, and this dose inhibits 5–10% of brain AChE in the pups when measured 2 hours after the last dose (*e.g.,* Refs. 34, 37, and 41). In another study of chlorpyrifos administered in feed to pregnant rats, the lowest intake of 0.36 mg/kg/d produced about 20–25% RBC ChE inhibition in the dams (Ref. 42). Currently there are no animal studies that support or dispute the potential for adverse neurodevelopmental outcomes at lower doses that do not inhibit AChE at any time, since this has not been adequately studied.

Overall, across the literature on neurodevelopmental outcomes and including most recent publications, there continue to be reports of effects on cognitive, anxiety/social behaviors, and motor activity. There are, however, inconsistencies in these effects with regards to dosing paradigms and gender-specificity. Studies report effects at doses that inhibit fetal/pup brain AChE activity to some degree, but there are also studies with no effects at the same doses. The broad profile of neurological effects that has been reported do not aid in the development of a specific AOP (AChE inhibition or other mechanisms), and existing experimental studies have not been designed to examine and track possible mechanisms from early initiating events to the final neurological outcome.

ii. Modes of action/adverse outcome pathways (MOA/AOP). Mode of action (MOA) and adverse outcome pathways (AOPs) describe a set of measureable key events that make up the biological processes leading to an adverse outcome and the causal linkages between such events. A review of the scientific literature on potential MOA/AOP leading to effects on the developing brain was conducted for the 2012 FIFRA SAP meeting (Ref. 10) and updated for the December 2014 chlorpyrifos RHHRA (Ref. 1). In short, multiple biologically plausible hypotheses and pathways are being pursued by researchers including: AChE as a morphogen; cholinergic system; endocannabinoid system; reactive oxygen species; serotonergic system; tubulin, microtubule associated proteins, and axonal transport. However, no one pathway has sufficient data to be considered more plausible than the others. Among the available studies, there are effects which are either as or more sensitive than AChE inhibition. The fact that there are, however, sparse data to support the *in vitro* to *in vivo* extrapolation, or the extrapolation from biological perturbation to adverse consequence significantly limits their quantitative

use in risk assessment. The SAP concurred with the agency in 2008 and 2012 about the lack of definable key events in a MOA/AOP leading to developmental neurobehavioral effects. The lack of an established MOA/AOP makes quantitative use of the epidemiology study in risk assessment challenging, particularly with respect to dose-response, critical duration of exposure, and window(s) of susceptibility. The agency will continue to monitor the scientific literature for studies on the MOA/AOP for neurodevelopmental effects.

iii. Epidemiology studies in mothers and children. In the chlorpyrifos RHHRA, EPA included epidemiologic research results from three prospective birth cohort studies. These include: (1) The Mothers and Newborn Study of North Manhattan and South Bronx performed by the Columbia Children's Center for Environmental Health (CCCEH) at Columbia University; (2) the Mt. Sinai Inner-City Toxicants, Child Growth and Development Study or the ''Mt. Sinai Child Growth and Development Study'' (Mt. Sinai); and (3) the Center for Health Assessment of Mothers and Children of Salinas Valley (CHAMACOS) conducted by researchers at University of California Berkeley. In these epidemiology studies, mother-infant pairs were recruited for the purpose of studying the potential health effects of environmental exposures during pregnancy on subsequent child development. Importantly, each of these cohorts evaluated the association between prenatal chlorpyrifos or OP exposure with adverse neurodevelopmental outcomes in children through age 7 years.

These studies reflect different types of exposed groups in the total population which strengthens the weight of the evidence considerations regarding this stream of information. The CCCEH Mother's and Newborn study and the Mt. Sinai Child Growth and Development study participants were likely exposed to OPs through the diet and through residential use of the pesticide for indoor pest control. In the residential setting, study populations were most likely exposed through indoor residential use of the pesticide during the study time period and additionally exposed to OPs via the oral route through ingesting residues in the diet and from hand-to-mouth contact with in-home surfaces, as well as possible dermal or inhalation exposure through contact with treated areas in the home environment (Refs. 43, 44, 45, and 46). In contrast, CHAMACOS cohort participants were employed as farm laborers or were residing in homes with farm laborers. The CHAMACOS study participants likely experienced exposure to OPs through the diet and from occupational exposure (primarily inhalation and dermal routes), as well as probable indirect take-home exposures (the ''tracking in'' of pesticide residues through shoes and clothing, augmented by poor hygiene practices) (Ref. 47). In each of the three U.S. children's health cohorts, EPA has considered the strengths and limitations of these studies, and believes that random or systematic errors in the design, conduct or analysis of these studies were unlikely to fully explain observed positive associations between *in utero* OP exposure and adverse neurodevelopmental effects observed at birth and through childhood (age 7 years). EPA believes these are strong studies which support a conclusion that OPs likely played a role in these outcomes.

These cohort studies each enrolled pregnant women during roughly the same time period, measured both environmental exposure to the pesticide during pregnancy and also measured biomarkers representing internal dose during pregnancy and at delivery, and prospectively assessed associations in their newborns and young children through age 7 years. Each study includes several hundred (approximately 100–400) mother-infant pairs; these sample sizes are sufficient to perform statistically valid analyses. Investigators from each study cohort utilized a similarly strong study design (prospective birth cohort); measured pesticide exposure using several different methods including environmental indicators as well as specific and non-specific biomarkers of OPs; ascertained developmental outcomes using validated assessment tools well-established in both clinical and research settings; and, measured, analyzed, selected and statistically adjusted for potentially confounding variables including socio-economic status and other environmental exposures using reasonable and appropriate methods. Limitations exist as well. These studies utilized a one-time measure (or the average of two measures) of chlorpyrifos or OP exposure to assess prenatal pesticide exposure throughout the gestational period, were unable to assess the influence of mixtures (co-occurring exposures in the relevant biological time window), and reflect a small sample size to fully evaluate the effect of more than one simultaneous exposure on neurodevelopment, *i.e.,* evidence of effect modification.

As noted, two major uncertainties in environmental epidemiology studies are the accurate and reliable measurement of exposure and potential confounding variables such as the influence of mixtures. The researchers with each of the three cohorts have provided supplemental methodological research to address these areas to the extent possible. Across the three children's health cohorts, study authors measured biomarkers of OP exposure. There is uncertainty as to the extent measurement of non-specific metabolites of OP or chlorpyrifos accurately reflects OP exposure; CCCEH and Mt. Sinai studies do not estimate post-natal exposure to chlorpyrifos among child participants, therefore the influence of early life and childhood OP exposure is unaccounted for in these analyses. The CHAMACOS cohort measured urinary levels of dialkyl phosphates (DAPs) in young children and did not observe negative significant associations in relation to neurodevelopment from post-natal exposure (Ref. 48). The CHAMACOS cohort investigators also measured AChE and butyl ChE as supplemental indicators of OP exposure.

Potential confounding bias is another major uncertainty within environmental epidemiology studies. Confounding variables, exposures that could be related to OP exposure and neurodevelopmental outcomes such as blood lead, may result in an incorrect epidemiological risk estimate. Across these cohort studies, investigators collected relevant information concerning demographic characteristics and other environmental exposures, and were, to the extent possible with the existing information, able to effectively hold constant the influence of these other variables when estimating the association between prenatal chlorpyrifos and adverse neurodevelopmental outcomes. Control of these variables is important to reduce the chances of a false positive study result. Overall, statistical analyses were judged to be appropriate and reasonable (not overly large number of statistical model variables) to the research question by EPA and expert Panel reviews (Refs. 9 and 10).

Researchers with both the Mt. Sinai and CHAMACOS cohorts evaluated neonatal neurological functioning in association with prenatal OP exposure; CCCEH did not conduct these measurements. To measure indices of abnormal neonatal behavior and/or neurological integrity, the Mt. Sinai and CHAMACOS authors used outcome measures derived from the Brazelton Neonatal Behavioral Assessment Scale

(BNBAS), a neurological assessment of 28 behavioral items and 18 primitive reflexes. This tool was administered to infants 2–5 days post-partum by trained neonatologists in the hospital setting using similar environmental conditions. The authors with both study groups observed an increased number of abnormal reflexes in relation to increasing measures of OP exposure (Refs. 49 and 50). Among the other 27 measures in the BNBAS, neither study group reported evidence of any other positive associations. The authors also observed evidence of potential effect modification by PON1 activity level in the relation between DAPs and neonatal neurodevelopment in which infants of mothers who are slower metabolizers have greater risk of abnormal reflexes (Refs. 49 and 50). However, EPA notes these studies are likely under-powered to make a statistically robust estimate of this statistical interaction.

Researchers across the three children's health cohorts utilized the Bayley Scales of Infant Development II (BSID–II) to generate a Mental Development Index (MDI) and a Psychomotor Development Index (PDI) to assess neurodevelopment in early childhood. In the CCCEH Mothers and Newborn study, Rauh *et al.* (Ref. 51) investigated MDI and PDI at 12, 24, and 36 months of age. Children were categorized as having either high (>6.17 pg/g) or low (≤6.17 pg/g) prenatal chlorpyrifos exposure, using categories informed by results of the previous study on birth characteristics (Ref. 52). Authors reported that the difference in MDI scores was ''marginally significant'' (p = 0.06) between the ''high'' and ''low'' exposed groups; the high exposed group scoring an average of 3.3 points lower than the low exposed (Ref. 51). Regarding the PDI score (motor skills), none of the 12 or 24 month PDI scores showed significant effects, but the 36 month score was significantly related to chlorpyrifos exposure. Researchers noted that the effects were most pronounced at the 36 month testing period. Within the 36 month testing period, the likelihood of highly exposed children developing mental delays were significantly greater (MDI: 2.4 times greater (95% CI: 1.12–5.08, p = 0.02) and PDI: 4.9 times greater (95% CI: 1.78–13.72; p = 0.002)) than those with lower prenatal exposure (Id.). Within the Mt. Sinai study, authors administered the BSID–II to participating children at 12 and 24 months and observed that prenatal total DAP metabolite level was associated with a decrement in mental development at 12 months among blacks and Hispanic children; however, these associations either attenuated or were non-existent at the 24-month visit (Ref. 52). In the CHAMACOS cohort, Eskenazi *et al.* (Ref. 53) observed that prenatal DAP levels were adversely associated with MDI, and at 24 months of age these associations reached statistical significance. In this study, neither prenatal DAPs nor maternal TCPy were associated with PDI (motor skills), nor did authors observe evidence of different risk by PON1 status. (Ref. 54).

With respect to the findings related to the autism spectrum, from CCCEH, Rauh *et al.* (Ref. 51) reported a statistically significant odds ratio for pervasive developmental disorder (PDD) (OR = 5.39; 95% CI: 1.21–24.11) when comparing high to low chlorpyrifos exposure groups. As described above, among 7–9 years old children in the Mt. Sinai Cohort (Ref. 55), there was no overall statistically significant association between maternal third trimester urinary DAP metabolite levels and reciprocal social responsiveness. However, some evidence of modification of the association between prenatal OP pesticide exposure and impaired social responsiveness in early childhood was observed by both race/ethnicity and child sex, with an association between diethyl alkylphosphate (DEAP) and poorer social responsiveness observed among black participants and boys. No association was observed among whites or Hispanics, among girls, or for DAP or dimethyl alkylphosphate (DMAP) biomarker levels. In the CHAMACOS cohort, Eskenazi *et al.* (Ref. 54) reported non-significant, but suggestive, increased odds of PDD of 2.0 (0.8 to 5.1; p = 0.14), whereas Eskenazi *et al.* (Ref. 53) reported a statistically significant association between total DAP exposure and increased odds of PDD.

With respect to attention problems, Rauh *et al.* (Ref. 50) also investigated 36-month child behavior checklist (CBCL) (behavioral) scores. Significant differences were observed between the high and low chlorpyrifos exposure groups in the general category of attention-problems (p = 0.010), and in the more specific DSM–IV (Diagnostic and Statistical Manual of Mental Disorders version IV) scale for ADHD problems (p = 0.018). The CHAMACOS cohort also investigated attention problems in early childhood using three different assessment tools: maternal report of child behavior at 3.5 and 5 years of age; direct assessment of the child at 3.5 and 5 years; and by a psychometrician's report of the behavior of the child during testing at 5 years. In this study population, higher concentrations of OP metabolites in the urine of pregnant women were associated with increased odds of attention problems and poorer attention scores in their children at age 5 years. (Ref. 53).

To measure intelligence among school aged children, authors from each of the three children's health cohorts used the Wechsler Intelligence Scale for Children, 4th edition (WISC–IV). The instrument measures four areas of mental functioning: The Verbal Comprehension Index, the Perceptual Reasoning Index, the Working Memory Index, and the Processing Speed Index. A Full-Scale IQ score combines the four composite indices. WISC–IV scores are standardized against U.S. population-based norms for English and Spanish-speaking children. In the CCCEH Mothers and Newborn Study, Rauh *et al.* (Ref. 56) evaluated the relationship between prenatal chlorpyrifos exposure and neurodevelopment among 265 of the cohort participants who had reached the age of 7 years and had a complete set of data including prenatal maternal interview data, prenatal chlorpyrifos marker levels from maternal and/or cord blood samples at delivery, postnatal covariates, and neurodevelopmental outcome data (Ref. 56). While models were developed using continuous measures of both prenatal chlorpyrifos exposure and Wechsler scores, for ease of interpretation, investigators reported that for each standard deviation increase in exposure (4.61 pg/g) there is a 1.4% reduction in Full-Scale IQ and a 2.8% reduction in Working Memory. In the Mt. Sinai study, prenatal maternal DEP urinary metabolite concentrations were associated with slight decrements in Full Scale Intelligence Quotient (FSIQ), Perceptual Reasoning, and Working Memory between the ages of 6 and 9 years, and difference in intelligence measures by putative PON1 status were also noted. (Ref. 52). Similarly, in the CHAMACOS cohort, Bouchard *et al.* (Ref. 57) observed evidence of an association between prenatal exposures to OPs as measured by urinary DAP (total DAP, DEP, and DMP) metabolites in women during pregnancy, and decreased cognitive functioning in children at age 7. In this study, children in the highest quintile of maternal DAP concentrations had a statistically significant 7 point difference in IQ points compared with those in the lowest quintile.

To ascertain whether observed differences in neurodevelopment after prenatal chlorpyrifos exposure may be explained by differences in brain morphology between exposed groups,

the CCCEH study investigators compared MRI brain images between high and low chlorpyrifos exposed child study participants. (Ref. 58). Authors determined there were distinct morphological differences in brain areas associated with these neurodevelopmental outcomes. The pilot study included 40 child participants due to strict inclusion and exclusion criteria, and the high cost of performing the imaging studies on each child. EPA convened a Federal Panel of experts to perform a written peer-review of this study. (Ref. 59). The Federal Panel concurred with the authors' conclusions in general; however the Federal Panel also noted that significantly greater and more sophisticated MRI imaging studies would be needed to link the morphological changes indicated in this study with specific functional outcomes noted in the CCCEH IQ study. Therefore, while generally supportive of the epidemiologic findings, additional study is needed to make specific links with areas of brain development change.

In sum, across these three children's environmental health studies, authors consistently identified associations with neurodevelopmental outcomes in relation to OP exposure. There is evidence of delays in mental development in infants (24–36 months), attention problems and autism spectrum disorder in early childhood, and intelligence decrements in school age children who were exposed to chlorpyrifos or OPs during gestation. Investigators reported strong measures of statistical association across several of these evaluations (odds ratios 2–4 fold increased in some instances), and observed evidence of exposures-response trends in some instances, *e.g.,* intelligence measures.

7. *Weight-of-Evidence Analysis Across Multiple Lines of Evidence.* The discussion above summarized key scientific information on two different adverse health outcomes: AChE inhibition and potential neurodevelopmental effects. The agency has conducted a weight-of-evidence (WOE) analysis utilizing the draft ''Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment'' in an effort to integrate this information in the development of an appropriate PoD for chlorpyrifos. That assessment focuses on two key scientific questions: (1) The degree to which scientific data suggest that chlorpyrifos causes long-term neurodevelopmental effects from fetal or early life exposure and (2) the degree to which adverse effects can be attributed to doses lower than those which elicit 10% inhibition of AChE, *i.e.,* the dose levels previously used for regulatory decision making.

i. *Dose-response relationships and temporal concordance.* Since the MOA(s)/AOP(s) is/are not established for neurodevelopmental outcomes, it is not possible to describe the concordance in key events or biological steps leading to neurodevelopmental outcomes. As such, the quantitative linkages between molecular initiating events, intermediate steps, and ultimately the adverse outcome (*i.e.,* neurodevelopmental effects) cannot be determined. Experimental toxicology studies in rodents suggest that long-term effects from chlorpyrifos exposure may occur. Due to the dose selections in most of these *in vivo* studies evaluating effects such as behavior and cognition, it is not known whether such adverse effects would be shown at doses lower than those which elicit 10% RBC AChE inhibition. It is notable, however, that comparing the lowest NOAEL observed in the *in vivo* animal studies (0.2 mg/kg/day; Ref. 60) for the neurodevelopmental outcomes to the repeated dosing reliable $BMDL_{10}$ ranging from 0.05–0.17 mg/kg/day for RBC AChE inhibition suggests that neurodevelopmental outcomes may occur in the same range as AChE inhibition in rat.

Within the epidemiology studies, the relationship in time between prenatal chlorpyrifos exposure and adverse neurodevelopmental outcomes is concordant. Specifically, with regard to the children's environmental health epidemiology studies, each of the three study cohorts utilized a prospective birth cohort study design in which mothers were recruited into study prior to the birth of the infants and development and identification of adverse effects; therefore, it is known with certainty that exposure preceded effect. In addition, because the time period under study within these cohorts, and specifically the CCCEH study, spanned the point in time in which pesticide manufacturers voluntarily cancelled the use of chlorpyrifos in the home environment, researchers were able to show the change in exposure before (high use period) and after (low/no use period) the period of removal of chlorpyrifos products from the residential marketplace. Moreover, prior to the voluntary cancellation there were >80% detectable levels of chlorpyrifos in cord blood but in the time period after the cancellation only 16% of the measured values were greater than the LOD; there was only one child born in the time period subsequent to the voluntary cancellation of chlorpyrifos in the residential marketplace for whom the cord blood chlorpyrifos level was in the upper-tertile of pre-cancellation exposure levels. The significantly reduced proportion of measured values greater than the limit of detection as well as the observation of an absence of an association between prenatal chlorpyrifos exposure and neurodevelopmental outcomes among infants born after the voluntary cancellation of chlorpyrifos support the hypothesis that chlorpyrifos is related to these outcomes. However, as noted by study authors, EPA, and the FIFRA SAP (Ref. 10), this could also be due to an inadequate sample size to detect a small to modest effect among the group of infants born after the voluntary cancellation.

With respect to the timing of exposure, the cord blood and other (meconium) measures from the CCCEH study provide evidence that exposure did occur to the fetus during gestation but the actual level of such exposure during the critical window(s) of susceptibility is not known. While significant uncertainties remain about the actual exposure levels experienced by mothers and infant participants in the three children's health cohorts, particularly during the time period prior to the voluntary cancellation of indoor residential uses of chlorpyrifos, exposures measured in the range reported in the epidemiology studies (pg/g plasma) are likely low enough that they were unlikely to have resulted in AChE inhibition. The FIFRA SAP (Ref. 10) concurred with the conclusion that measured levels of chlorpyrifos among epidemiology study participants were unlikely to have resulted in AChE inhibition. The urinary TCPy concentrations among mothers were comparable to the general population levels measured in NHANES. Comparing cord blood concentrations with the concentrations in which AChE inhibition was observed in adult volunteers indicates AChE inhibition would likely not have occurred at levels observed in the epidemiology studies (6.17 pg/g). Therefore, while uncertainty exists as to actual chlorpyrifos exposure at (unknown) critical windows of exposure, EPA believes it is unlikely mothers enrolled in the birth cohort studies experienced RBC AChE inhibition (greater than 10%).

The biomarker data from the CCCEH studies are supported by EPA's dose reconstruction analysis using the PBPK–PD model, which support a conclusion that indoor application of chlorpyrifos, when used as allowed prior to cancellation from the residential

marketplace in 2000, likely would not have resulted in RBC AChE inhibition greater than 10% in pregnant women or young children.

ii. Strength, consistency, and specificity. As stated in the EPA neurotoxicity guidelines (Ref. 61), direct extrapolation of developmental neurotoxicity results from laboratory animals to humans is limited by the lack of knowledge about underlying toxicological mechanisms and the relevance of these results to humans. EPA notes consistencies across these two databases, although challenges of making a direct comparison between neurodevelopmental domain inter-species remain. It can be assumed that developmental neurotoxicity effects in animal studies indicate the potential for altered neurobehavioral development in humans, although the specific types of developmental effects seen in experimental animal studies may not be the same as those that may be produced in humans. However, considering the toxicological and epidemiological data in the context of three major neurodevelopmental domains (specifically, cognition, motor control, and social behavior), insights can be gained. For example, chlorpyrifos studies in rats and/or mice have reported impaired cognition (spatial learning and working memory; *e.g.,* Refs. 35 and 38); changes in locomotor activity levels (exploration, rearing; *e.g.,* Refs. 36 and 62); altered social interaction (aggression, maternal behavior; Refs. 63 and 64); and effects on brain morphometrics (Refs. 65 and 66). Similarly, epidemiologic investigations have reported effects on cognition (Bayley scale indices; Refs. 50 and 53), abnormal motor development in neonates (reflexes, Brazelton score; Refs. 49 and 48), altered social development (*e.g.,* ADHD; Refs. 50 and 67), and MRI brain scans (Ref. 68). It is notable that the laboratory animal studies vary in experimental designs such as species, strain, gender, dosing regimens (age, routes, vehicle), and test parameters (age, protocol). Likewise, observational epidemiology studies vary by population characteristics (race/ethnicity, socio-economic status (SES), and pesticide use/exposure profile), co-exposures (mix of chemicals, windows of exposure), and method of exposure and outcome assessment. Given the differences across laboratory animal and epidemiology studies, the qualitative similarity in research findings is striking.

In contrast, quantitatively, there are notable differences between animals and humans. Specifically, in animals, the doses most often used in the behavior studies (1 and 5 mg/kg/day) are sufficient to elicit approximately ≥10% brain AChE inhibition and ≥30% in RBC AChE inhibition, depending on the study design, age of the animal, and sampling time. In the epidemiology studies, based on the comparisons with biomonitoring data and the results of the dose-reconstruction analysis, it is unlikely that RBC AChE would have been inhibited by any meaningful or measurable amount, if any at all, and most likely none in the brain. This key difference in dose response between the experimental toxicology and epidemiology studies poses challenges in interpreting such data. There are a number of possible hypotheses such as: (1) Limitations of experimental laboratory studies which have limited statistical power due to relatively small sample sizes; (2) humans display a broader array of behaviors and cognitive abilities than rats, thus limiting the sensitivity of the rat studies; and (3) in the epidemiology studies, the timing of chlorpyrifos application and blood collections are not coupled—thus higher levels of blood chlorpyrifos were likely missed (albeit the results of the dose reconstruction analysis reduce the likelihood of this hypothesis).

In making a weight-of-the-evidence analysis, it is important to consider the strength of the statistical measures of association between prenatal chlorpyrifos exposure and adverse neurodevelopmental outcomes through childhood (epidemiology) and possibly into adulthood (animal studies). It is also important to consider the strength of the integrated qualitative and quantitative evidence, the consistency of the observed associations across epidemiology studies and considering both animal and human data support the conclusion that chlorpyrifos plays a role in adverse neurodevelopmental outcomes. While it cannot be stated that chlorpyrifos alone is the sole contributor to the observed outcomes (specificity), since other environmental, demographic or psychosocial exposures may also play a part in these outcomes, this does not obviate the contribution of prenatal chlorpyrifos exposure in the development of adverse neurodevelopmental outcomes as echoed by the FIFRA SAP (Ref. 10).

The CCCEH study, which measures chlorpyrifos specifically, provides a number of notable associations. Regarding infant and toddler neurodevelopment, the CCCEH authors also reported statistically significant deficits of 6.5 points on the Bayley Psychomotor Development Index (PDI) at 3 years of age when comparing high to low exposure groups (Ref. 50). Notably these decrements in PDI persist even after adjustment for group and individual level socioeconomic variables (Ref. 69). These investigators also observed increased odds of mental delay (OR = 2.4; 95% CI: 1.1–5.1) and psychomotor delay (OR = 4.9; 95% CI: 1.8–13.7) at age three when comparing high to low exposure groups. (Ref. 50). Rauh *et al.* (Ref. 50) also reported large odds ratios for attention disorders (OR = 11.26; 95% CI: 1.79–70.99), ADHD (OR = 6.50; 95% CI: 1.09–38.69), and PDD (OR = 5.39; 95% CI: 1.21–24.11) when comparing high to low chlorpyrifos exposure groups. (Ref. 50). EPA notes that the magnitude of these results are so large that they are unlikely to be affected by residual confounding although limited sample sizes resulted in imprecise estimates.

Decrements in intelligence measures were identified in relation to increasing levels of prenatal chlorpyrifos exposure. The CCCEH study reported statistically significant decreases of 1.4% in full scale IQ and 2.8% in working memory among seven-year olds for each standard deviation increase in chlorpyrifos exposure. (Ref. 56). These results persist even when performing sensitivity analyses including only those with detectable chlorpyrifos levels.

iii. Biological plausibility and coherence. Although MOA(s)/AOP(s) has/have not been established for neurodevelopmental outcomes, the growing body of literature does demonstrate that chlorpyrifos and/or its oxon are biologically active on a number of processes that affect the developing brain. Moreover, there is a large body of *in vivo* laboratory studies which show long-term behavioral effects from early life exposure. EPA considers the results of the toxicological studies relevant to the human population, as qualitatively supported by the results of epidemiology studies. The lack of established MOA/AOP does not undermine or reduce the confidence in the findings of the epidemiology studies. The CCCEH study data are not considered in isolation, but rather are strengthened when considered in concert with the results from the other two cohort studies, as noted by the FIFRA SAP. (Ref. 10). As noted above, the CHAMACOS and Mt. Sinai cohorts that measured neurological effects at birth (the Brazelton index), observed a putative association with chlorpyrifos. (Ref. 48 and 49). Similarly, while not consistent by age at time of testing (ranging from 6 months to 36 months across the three cohorts), each cohort reported evidence of impaired mental and psychomotor development. Attentional problems and ADHD were

reported by both Columbia and CHAMACOS investigators. Finally, each of the three cohort study authors observed an inverse relation between the respective prenatal measures of OP and intelligence measures at age 7 years.

iv. Weight of evidence conclusions. Key issues being considered by the Agency in its weight-of-evidence evaluation of chlorpyrifos toxicity are (1) whether chlorpyrifos causes long-term effects from fetal or early life exposure and (2) whether adverse effects can be attributed to doses lower than those which elicit 10% inhibition of AChE—EPA's current regulatory point of departure for chlorpyrifos and other OPs. When taken together the evidence from (1) the experimental toxicology studies evaluating outcomes such as behavior and cognitive function; (2) mechanistic data on possible adverse outcome pathways/modes of action; and (3) epidemiologic and biomonitoring studies leads the agency to the following conclusions:

- Qualitatively, these lines of evidence together support a conclusion that exposure to chlorpyrifos results in adverse neurodevelopmental outcomes in humans, at least under some conditions.
- Quantitatively, the dose-response relationship of AChE inhibition across different life stages is established, but MOAs/AOPs for neurodevelopmental outcomes are not established.
- The database of *in vivo* animal toxicology neurodevelopmental studies on adverse outcomes includes only a small number of studies at doses lower than 1 mg/kg/day. Despite this, the agency noted that the BMD values in adult (pregnant and nonpregnant) female rats (0.05–0.15 mg/kg/day) are generally 10-fold or more lower than the doses where effects on neurodevelopmental outcomes in laboratory rats are observed.
- With respect to the mechanistic data, there are sparse data to support the *in vitro* to *in vivo* extrapolation, or the extrapolation from biological perturbation to adverse consequence, which significantly limits their quantitative use in risk assessment.
- As noted above, the lack of an established MOA/AOP makes quantitative use of the epidemiology study in risk assessment challenging, particularly with respect to dose-response, critical duration of exposure, and window(s) of susceptibility. Despite this uncertainty, the cord blood and other measures (meconium) provide evidence of exposure to the fetus during gestation. Moreover, exposure levels in the range measured in the epidemiology studies (pg/g) are likely low enough that they are unlikely to result in AChE inhibition, as supported by the dose reconstruction analysis of residential use prior to 2000 (although the agency has not investigated the degree to which exposure to multiple AChE-inhibiting pesticides indoors simultaneously could impact this conclusion).
- Given the totality of the evidence, the agency concludes that chlorpyrifos likely played a role in the neurodevelopmental outcomes reported in the CCEH study but uncertainties such as the lack of an established MOA/AOP for neurodevelopmental effects and the exposure to multiple AChE-inhibiting pesticides precludes definitive causal inference.
- In light of the uncertainties regarding the relationship of observed neurodevelopmental outcomes to AChE inhibition, EPA is retaining the 10X FQPA safety factor.

Following publication of the December 2014 RHHRA, EPA received public comments suggesting that the uncertainty surrounding the dose-response relationship for neurodevelopmental effects warranted the application of a larger safety factor than the statutory default 10X factor. The commenters suggested that EPA's assessment had failed to establish that, even with the retained 10X FQPA safety factor, exposures to chlorpyrifos will not result in adverse neurodevelopmental outcomes. Some of the commenters suggested that EPA evaluate available biomonitoring from the epidemiologic data to help assess whether these outcomes could in fact be occurring at levels below EPA's PAD that it is using for purposes of this proposed rule. EPA is currently in the process of evaluating the available biomonitoring; however, in light of the August 10, 2015 *PANNA* decision that orders EPA to respond to the PANNA–NRDC Petition not later than October 31, 2015, EPA has not been able to complete that evaluation in advance of this proposal. EPA is continuing its evaluation of the available biomonitoring and will update this action to reflect the results of that review, if warranted.

Further, EPA is aware that some commenters on EPA's RHHRA believe the PBPK–PD model used to derive PoDs is inappropriate for the evaluation of neurodevelopmental effects, given that there is no established association between AChE inhibition and long term adverse neurodevelopmental outcomes observed in recent epidemiology studies. While EPA's evaluation of biomonitoring from available human epidemiology studies will not help to further determine the MOA/AOP for these adverse neurodevelopmental outcomes, as noted, it will help EPA better assess whether the doses (PADs) EPA is proposing to use for regulatory purposes in this proposed rule are protective for potential adverse neurodevelopmental effects. While, as noted, that assessment is still not complete, because EPA is proposing to revoke all tolerances in this proposed rule based on its concern regarding AChE inhibition, it is unnecessary for EPA to determine at this time whether its current PADs bound the chlorpyrifos exposures measured in the epidemiology studies. In any case, as EPA completes its further evaluation it will update this action, as warranted.

B. Dietary Exposure and Risk Assessment.

The general approach for the chlorpyrifos dietary exposure and risk assessment is as follows: The PBPK–PD model was used to predict acute (24 hour) and steady state (21-day) PoDs which correspond to 10% RBC AChE inhibition for the lifestages relevant to chlorpyrifos risk assessment. The PoDs are then divided by the total uncertainty factor to determine the PAD.

For the dietary risk assessment for food only, the exposure values resulting from Dietary Exposure Evaluation Model (DEEM) and the Calendex model are compared to the PBPK–PD-based acute PAD and steady state PAD, respectively. When estimated dietary risk estimates exceeds 100% of the PAD there is generally a risk concern.

For the dietary assessment for water, a drinking water level of comparison (DWLOC) approach to aggregate risk was used to calculate the amount of exposure available in the total 'risk cup' for chlorpyrifos oxon in drinking water after accounting for any chloropyrifos exposures from food and/or residential use.

1. Residues of concern. The qualitative nature of the residue in plants and livestock is adequately understood based on acceptable metabolism studies with cereal grain (corn), root and tuber vegetable (sugar beets), and poultry and ruminants. The residue of concern, for tolerance expression and risk assessment, in plants (food and feed) and livestock commodities is the parent compound chlorpyrifos.

Based on evidence (various crop field trials and metabolism studies) indicating that the metabolite chlorpyrifos oxon would be not be present in edible portions of the crops (particularly at periods longer than the currently registered PHIs), it is not a residue of concern in food or feed at this

time. Also, the chlorpyrifos oxon is not found on samples in the USDA PDP monitoring program. In fact, from 2007 to 2012, out of several thousand samples of various commodities, only one sample of potato showed presence of the oxon at trace levels, 0.003 ppm where the LOD was 0.002 ppm, even though there are no registered uses of chlorpyrifos on potato in the U.S.

The oxon metabolite was not found in milk or livestock tissues in cattle and dairy cow feeding studies, at all feeding levels tested, and is not a residue of concern in livestock commodities.

Oxidation of chlorpyrifos to chlorpyrifos oxon can occur through photolysis, aerobic metabolism, and chlorination as well as other oxidative processes. Because of the toxicity of the oxon and data indicating that chlorpyrifos rapidly converts to the oxon during typical drinking water treatment (chlorination), the drinking water risk assessment considers the oxon as the residue of concern in treated drinking water and assumes 100% conversion of chlorpyrifos to chlorpyrifos oxon. (Ref. 70). This approach of assuming 100% conversion of chlorpyrifos to the more toxic chlorpyrifos oxon, is a conservative approach and thus protective of other likely exposure scenarios of chlorpyrifos only and chlorpyrifos and chlorpyrifos oxon.

The chlorpyrifos degradate TCPy is not considered a residue of concern for this assessment as it does not inhibit cholinesterase (a separate human health risk assessment has been performed for TCPy, which has its own toxicity database). TCPy (derived from triclopyr, chlorpyrifos, and chlorpyrifos-methyl) was previously assessed on June 6, 2002. (Ref. 71).

2. Dietary (food only) risk assessment. The general approach for the chlorpyrifos (food only) exposure and risk assessment can be described as follows: The PBPK–PD model was used to predict acute (24 hour) and steady state (21-day) PoDs which correspond to 10% RBC AChE inhibition for the index lifestages relevant to chlorpyrifos risk assessment (children of various ages which differ due to exposure pattern, and adult females of childbearing age). The PoDs are then divided by the total uncertainty factor to determine the PAD. For food, the residue of concern is chlorpyrifos (the oxon metabolite is not an expected residue on foods). The chlorpyrifos total uncertainty factors are 100X for adult females (10X FQPA SF and 10X intra-species extrapolation factor) and 40X for the other populations (10X FQPA SF and 4X intra-species extrapolation factor). For the dietary risk assessment for food only, the exposure values resulting from Dietary Exposure Evaluation Model (DEEM) and the Calendex model are compared to the PBPK–PD-based acute PAD and steady state PAD, respectively. The chlorpyrifos exposure values resulting from dietary modeling are compared to the PAD. Dietary exposures greater than 100% of the PAD are generally cause for concern and would be considered ''unsafe'' within the meaning of FFDCA section 408(b)(2)(B).

i. Description of residue data used in dietary (food only) assessment. Acute and steady state dietary (food only) exposure analyses for chlorpyrifos were conducted using the Dietary Exposure Evaluation Model (DEEM) and Calendex software with the Food Commodity Intake Database (FCID) (Ref. 90). This software uses 2003–2008 food consumption data from NHANES/WWEIA. The most recent previous dietary assessment was conducted in support of the 2011 PHHRA and the ongoing chlorpyrifos registration review. (Ref. 72). This current analysis reflect the latest consumption data as well as more recent food monitoring and percent crop treated data. These analyses were performed for the purpose of obtaining food exposure values for comparison to the chlorpyrifos doses predicted by the PBPK–PD model to cause RBC ChEI. The acute and steady state exposure analyses do not include drinking water which is assessed separately as discussed in Unit VI.2.B.

Both the acute and steady state dietary exposure analyses are highly refined. The large majority of food residues used were based upon U.S. Department of Agriculture's PDP monitoring data except in a few instances where no appropriate PDP data were available. In those cases, field trial data were used or tolerance level residues were assumed. The same data were used for both the acute and steady state analyses. EPA also considered percent crop treated information. Food processing factors from submitted studies were used as appropriate.

The acute and steady state dietary exposure assessment used percent crop treated information from EPA's Screening Level Usage Analysis (Ref. 73) to estimate chlorpyrifos exposures from the consumption of food. Reported percent crop treated ranged from <2.5% to 70%. 100% crop treated was assumed for many crops for which no usage data were available.

ii. Acute dietary (food only) risk assessment. Chlorpyrifos acute (food only) dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM–FCID™, Version 3.16, which incorporates consumption data from NHANES/WWEIA. This dietary survey was conducted from 2003 to 2008. Acute dietary risk estimates are presented below for the sentinel population subgroups for acute risk assessment: infants (<1 year old), children (1–2 years old), youths (6–12 years old) and adults (females 13–49 years old). The assessment of these index lifestages will be protective for the other population subgroups.

As Table 2 indicates, EPA believes that acute dietary risk from food only does not present a significant risk, as estimates are all far below 100% of the acute PAD for food (aPADfood) at the 99.9th percentile of exposure. The subgroup with the highest risk estimate was females (13–49 years old) at 3.2% aPADfood.

TABLE 2—ACUTE DIETARY (FOOD ONLY) EXPOSURE AND RISK ESTIMATES FOR CHLORPYRIFOS

Population subgroup	$aPoD_{food}$ [1] (ug/kg/day)	$aPAD_{food}$ [2] (ug/kg/day)	Food exposure [3] (ug/kg/day)	Percent of $aPAD_{food}$
Infants (<1 yr)	600	15	0.273	1.8
Children (1–2 yrs)	581	14	0.423	3.0
Youths (6–12 yrs)	530	13	0.189	1.4
Adults (Females 13–49 yrs)	469	4.7	0.150	3.2

[1] Acute point of departure; daily dose predicted by PBPK–PD model to cause RBC ChEI of 10% for acute dietary (food) exposures.

[2] aPAD = acute PAD = PoD (Dose predicted by PBPK–PD model to cause 10% RBC ChEI) ÷ total UF; Total uncertainty factor = 100X for females 13–49 years (10X intraspecies factor and 10X FQPA safety factor) and 40X for other populations (4X intraspecies factor and 10X FQPA safety factor).

[3] Acute food only exposure estimates from DEEM (at 99.9th percentile). Refined with monitoring data and %CT.

iii. Steady state detary (food only) risk assessment. A chlorpyrifos steady state dietary (food only) exposure analysis was conducted using Calendex-FCID™. EPA's steady state assessment considers the potential risk from a 21-day exposure duration using a 3-week rolling average (sliding by day) across the year. For this assessment, the same food residue values used in the acute assessment were used for the 21-day duration. In the Calendex software, one diary for each individual in the WWEIA is selected to be paired with a randomly selected set of residue values for each food consumed. The steady state analysis calculated exposures for the sentinel populations for infant, child, youths, and adult (infants <1 year, children 1–2 years, youths 6–12 years, females 13–49 years).

Calendex reported dietary exposures for each population subgroup at several percentiles of exposure ranging from 10th percentile to 99.9th percentile. Similar to acute risks, the dietary (food only) exposures for chlorpyrifos were all well below 100% ssPADfood (all populations, at all percentiles of exposure). Only the 99.9th percentile of exposure is presented in Table 3. For the steady state dietary (food only) exposure analyses, children (1–2 years old) was the population subgroup with the highest risk estimate at 9.7% of the ssPADfood at the 99.9th percentile of exposure.

TABLE 3—STEADY STATE DIETARY (FOOD ONLY) EXPOSURE AND RISK ESTIMATES FOR CHLORPYRIFOS

Population subgroup	$_{SS}$ PoD_{food} [1] (ug/kg/day)	$ssPAD_{food}$ [2] (ug/kg/day)	Food exposure [3] (ug/kg/day)	Percent of $ssPAD_{food}$
Infants (<1 yr)	103	2.6	0.186	7.2
Children (1–2 yrs)	99	2.5	0.242	9.7
Youths (6–12 yrs)	90	2.2	0.128	5.8
Adults (Females 13–49 yrs)	78	0.78	0.075	9.6

[1] Steady state point of departure; daily dose predicted by PBPK–PD model to cause RBC ChEI of 10% for steady state (21-day) dietary (food) exposures.

[2] ssPAD = Steady state PAD = PoD (Dose predicted by PBPK–PD model to cause 10% RBC ChEI) ÷ total UF; Total uncertainty factor = 100X for females 13–49 years (10X intraspecies factor and 10X FQPA safety factor) and 40X for other populations (4X intraspecies factor and 10X FQPA safety factor).

[3] Steady state (21-day) food only exposure estimates from Calendex (at 99.9th percentile). Refined with monitoring data and %CT.

As Tables 2 and 3 make clear, EPA does not believe that food exposures to chlorpyrifos by themselves present a significant risk of AChE inhibition. Based on the analysis above, EPA would therefore not be proposing the revocation of chlorpyrifos if dietary exposures were confined to food. As outlined below, however, EPA believes that for some portions of the country, food exposures, when aggregated with residential exposures and potentially more significant drinking water exposures, do present a significant risk concern and support revocation of all chlorpyrifos tolerances.

iv. Residential (non-occupational) exposure/risk characterization. As explained above in Unit V.B.3., in assessing dietary risk under the FFDCA, EPA must consider not only direct dietary exposure from food and drinking water, but also non-occupational exposures to the pesticide, such as residential exposure and bystander exposure from the use of agricultural pesticides. For simplicity, EPA refers to its assessment of all such exposures as its ''residential exposure assessment.'' For chlorpyrifos, the vast majority of residential use products were cancelled as of 2001. Current chlorpyrifos residential uses now include a granular fire ant mound use (commercial applicator only) and ant and roach bait in child-resistant packaging (homeowner applicator). Additionally, chlorpyrifos is labeled for public health aerial and ground-based fogger ULV mosquito adulticide applications and for golf course turf applications. For the purpose of residential exposure assessment, the parent compound chlorpyrifos is the residue of concern.

With respect to bystander exposure, EPA's worker protection standard prohibits using any pesticide in a way that will contact either workers or bystanders through spray drift. Further, in connection with EPA's 2012 spray drift evaluation, EPA imposed additional no-spray buffers to limit deposition of chlorpyrifos through drift in areas adjacent to agricultural fields where bystanders may be present following application. With respect to bystander exposure to volatilized (vapor form) chlorpyrifos following application, as noted in Unit VI.A., recently submitted rat acute toxicity studies of vapor phase chlorpyrifos along with available subchronic vapor phase inhalation studies support a conclusion that acute exposure to the saturated vapor of chlorpyrifos or its oxon do not result in hazard due to AChE inhibition. Accordingly, EPA concludes that with the additional no spray buffer restrictions, risk concerns to bystanders from spray drift have been eliminated and therefore bystander exposures are not included as part of EPA's aggregate risk assessment.

Residential Handler Exposure. EPA uses the term ''handlers'' to describe those individuals who are involved in the pesticide application process. EPA believes that there are distinct tasks related to applications and that exposures can vary depending on the specifics of each task. Residential (non-occupational) handlers are addressed somewhat differently by EPA as homeowners are assumed to complete all elements of an application without use of any protective equipment.

Based upon review of all chlorpyrifos registered uses, only the ant and roach bait products can be applied by a homeowner in a residential setting. Because the ant and roach bait products are designed such that the active ingredient is contained within a bait station, the potential for contact with the chlorpyrifos-containing bait material has been eliminated and therefore these products do not pose a risk concern.

Residential Post-Application Exposure. There is the potential for post-application exposures as a result of being in an environment that has been previously treated with chlorpyrifos. Chlorpyrifos can be used in areas frequented by the general population including golf courses and as an aerial and ground-based ULV mosquito adulticide applications made directly in

residential areas. Post-application exposure from residential fire ant mound treatment is not quantitatively assessed here as exposures are considered to be negligible and do not pose a risk concern; these products can only be applied professionally and EPA therefore does not anticipate direct non-occupational exposure with treated ant mounds.

In the RHHRA which supports this rule, EPA has updated the post-application exposure assessment to reflect: (1) Use of the PBPK–PD model for determining toxicological PoDs; (2) use of the 2012 Residential SOPs (Ref. 28); (3) use of the AgDISP model for estimation of airborne concentrations and residue dissipation following chlorpyrifos mosquito adulticide applications; (4) updated methodology for determining the airborne concentration of active ingredient following ground-based mosquito adulticide applications; and (5) use of updated body weights for all residential populations assessed.

In addition, EPA utilized only steady state durations of exposure in the updated residential assessment. The steady state endpoint selection for chlorpyrifos overlaps EPA's traditional short-term exposure duration endpoint selection and is considered health protective for both short- and intermediate-term exposures.

The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenarios:

Golf Course Use (Emusifiable Concentrate (EC) and Granular (G) Formulations)

- Children 6 to <11 years old, youths 11 to <16 years old, and adult post-application dermal exposure from contact with treated turf while golfing.

Public Health Mosquito Adulticide Use (Aerial and Ground Applications)

- Children 1 to <2 years old and adult post-application dermal exposure from contact with turf following the deposition of chlorpyrifos residues from public health mosquito adulticide application.
- Children 1 to <2 years old and adult post-application inhalation exposure from airborne chlorpyrifos following public health mosquito adulticide application.
- Children 1 to <2 years old post-application incidental oral (hand-to-mouth) exposure from contact with turf following the deposition of chlorpyrifos residues from public health mosquito adulticide application.
- Children 1 to <2 years old post-application incidental oral (object-to-mouth) exposure from contact with toys containing residues from turf following the deposition of chlorpyrifos residues from public health mosquito adulticide application.

The following assumptions and exposure factors served as the basis for completing the residential post-application risk assessment. These assumptions and factors are described in detail in the updated occupational and residential exposure and risk assessment. (Ref. 74).

Exposure Duration: Residential post-application exposures to chlorpyrifos are assumed to be steady state (*i.e.,* 21 days or longer).

The application of mosquitocide in residential areas may result in the potential for post-application inhalation exposures. The aerosolized particulate remaining following application is assumed to persist for no longer than one hour in proximity of the application source and, accordingly, would be most appropriately defined as acute in duration. However, this assessment assumes that post-application inhalation exposures are steady state which is a highly conservative approach given how infrequently mosquitocides are repeatedly applied to the same locations and how rapidly aerosols dissipate after these types of applications. The parameters used to define this exposure scenario in the PBPK–PD model conservatively reflect daily, one hour exposures for 21 days.

Application Rates: In order to seek clarification of chlorpyrifos usage, the agency compiled a master use summary document reflective of the use profile of all active product labels. The document, among other information, presents all registered uses of chlorpyrifos and corresponding maximum single application rates, equipment types, restricted entry intervals (REIs), etc. This assessment assumes that the detailed information on application rates and use patterns presented in Appendix 9 (Master Use Summary Document) in support of the 2014 RHHRA will be implemented on all chlorpyrifos labels and is the basis of the occupational and residential risk assessment. If, for any reason, the final chlorpyrifos labels contain higher application rates, the actual risks posed by those products may exceed the risks estimated in this assessment.

Body Weights: The body weights assumed for this assessment differ from those used in 2011 residential exposure assessment and are based on the recommendations of the 2012 Residential SOPs. These body weights are the same as selected for derivation of PBPK–PD PoDs for use in assessment of residential exposures.

The standard body weights are as follows: Youths 11 to <16 years old, 57 kg; children 6 to <11 years old, 32 kg; and children 1 to <2 years old, 11 kg. For adults when an endpoint is not sex-specific (*i.e.,* the endpoints are not based on developmental or fetal effects) a body weight of 80 kg is typically used in risk assessment. However, in this case, a female-specific body weight of 69 kg was used. While the endpoint of concern, RBC AChE inhibition, is not sex-specific, the female body weight was used due to concerns for neurodevelopmental effects related to early life exposure to chlorpyrifos.

Post-application exposures from golfing have been assessed using the 2012 Residential SOPs and with use of exposure data from a chemical-specific turf transferable residue (TTR) study. The study was conducted with an emulsifiable concentrate, a granular, and a wettable powder formulation. Only the emulsifiable concentrate and granular data were used because there are no currently registered wettable powder formulations. The study was conducted in 3 states, California, Indiana and Mississippi, with use of the emulsifiable concentrate and wettable powder formulations. Exposure was estimated by normalizing Day 0 TTR measures from study application rates to the current maximum application rate allowable by the label. Chlorpyrifos oxon residues were not analyzed.

The post-application exposure potential from public health mosquito adulticide applications has been considered for both ground based truck foggers and aerial applications. For assessment of the mosquito adulticide use, the algorithms and inputs presented in the 2012 Residential SOP Lawns/Turf section were used coupled with the available TTR data described above. The deposition of chlorpyrifos from these applications are not based on the application rate alone, but also using the AgDISP (v8.2.6) model (aerial applications, the currently recommended model for assessment of mosquito adulticide applications) or empirical data (ground applications) to determine how much pesticide is deposited on residential lawns as a result of mosquito adulticide treatments at the maximum application rates for each. The TTR data are then used to determine the fraction of the total residue deposited following the mosquitocide application which can result in exposures to impacted individuals. Inhalation exposures are also estimated using AgDrift for aerial

application and a recently developed well-mixed box (WMB) model approach for outdoor foggers.

EPA used the AgDISP (v8.2.6) model to estimate the deposition of chlorpyrifos from aerial applications and the airborne concentration of chlorpyrifos following public health mosquitocide application. AgDISP predicts the motion of spray material released from aircraft, and determines the amount of application volume that remained aloft and the amount of the resulting droplets deposited on the surfaces in the treatment area, as well as downwind from the treatment area. The model also allows for the estimation of air concentrations in the breathing zones of adults and children for use in calculating the post-application inhalation risks to individuals residing in areas being treated by aerial application of chlorpyrifos. The aerial fraction of the mosquito adulticide application rate applied (0.010 lb ai/A) is 0.35 (*i.e.,* 35 percent of application rate is deposited on turf); and the airborne concentration at the breathing height of adults and children of chlorpyrifos 1 hour following aerial mosquito adulticide application is 0.00060 mg/m3.

EPA used empirical data to derive the ground-based deposition of chlorpyrifos following public health mosquitocide application. These data, conducted by Moore *et al.* (Ref. 75) and Tietze *et al.* (Ref. 76), measured the deposition of malathion via ULV ground equipment as applied for mosquito control. Based on these data, EPA used an off-target deposition rate of 5 percent of the application rate to evaluate ground-based ULV applications (*i.e.,* 5 percent of the target application rate deposits on turf). A value slightly higher than the mean values for both studies was selected because of the variability in the data and the limited number of data points. The adjusted application rate was then used to define TTR levels by scaling the available TTR data as appropriate.

In order to calculate airborne concentrations from ULV truck fogger applications, EPA used the 2012 Residential SOPs for Outdoor Fogging/Misting Systems, with minimal modification to the well-mixed box (WMB) model. The WMB model allows for the estimation of air concentrations in the breathing zones of adults and children for use in calculating the post-application inhalation exposure to individuals residing in areas being treated by ground application of chlorpyrifos. This methodology is a modification of the previous method used in the 2011 occupational and residential exposure assessment to evaluate post-application inhalation exposure resulting from truck mounted mosquito fogger. The revised methodology more accurately accounts for dilution.

Combining Residential Exposure and Risk Estimates. Since dermal, incidental oral, and inhalation exposure routes share a common toxicological endpoint, RBC AChE inhibition risk estimates have been combined for those routes. The incidental oral scenarios (*i.e.,* hand-to-mouth, object-to-mouth, and soil ingestion) should be considered inter-related, as it is likely that these exposures are interspersed over time and are not each occurring simultaneously. Combining all three of these scenarios with the dermal and inhalation exposure scenarios would be unrealistic because of the conservative nature of each individual assessment. Therefore, the post-application exposure scenarios that were combined for children 1 <2 years old are the dermal, inhalation, and hand-to-mouth scenarios (the highest incidental oral exposure expected). This combination should be considered a protective estimate of children's exposure to pesticides.

Summary of Residential Post-application Non-Cancer Exposure and Risk Estimates. The assessment of steady state golfer post-application exposures (dermal only) to chlorpyrifos treated turf for the lifestages adults, children 6 to <11 years old, and youths 11 to <16 years old, results in no risks of concern (*i.e.,* children 6 to <11 and youths 11 to <16 years old, MOEs are ≥40; adults, MOEs are ≥100). For the assessment of post-application exposures from public health mosquitocide applications, no combined risks of concern were identified for adults (dermal and inhalation) and children 1 to <2 years old (dermal, incidental oral, and inhalation). A summary of risk estimates is presented in Table 4.

TABLE 4—RESIDENTIAL POST-APPLICATION NON-CANCER EXPOSURE AND RISK ESTIMATES FOR CHLORPYRIFOS

Lifestage	Post-application exposure scenario		Application rate [1]	State (TTR data)	Dose (mg/kg/day) [3]	MOEs [4]	Combined routes [5]	Combined MOEs [6]
	Use site	Route of exposure						
Adult (Females)	Golf Course Turf	Dermal	1.0 (Emulsifiable Concentrate).	CA	0.010	1,400	NA	NA
				IN	0.0069	2,100		
				MS	0.012	1,200		
				Mean	0.0095	1,500		
Youths 11 to <16 yrs old.				CA	0.010	1,600		
				IN	0.0069	2,300		
				MS	0.012	1,400		
				Mean	0.0096	1,700		
Children 6 to <11 years old.				CA	0.012	2,100		
				IN	0.0082	3,100		
				MS	0.014	1,800		
				Mean	0.011	2,200		
Adult (Females)			1.0 (Granular)	CA	0.0088	1,600		
Youths 11 to <16 yrs old.					0.0088	1,900		
Children 6 to <11 years old.					0.010	2,400		
Adult (Females)	Aerial and Ground Based ULV Mosquitocide Applications.	Dermal	0.010 (Aerial)	MS	0.00052	75,000	X	9,100
		Inhalation		NA	0.00060 (mg/m^3)	10,300	X	
Children 1 to <2 yrs old.	Mosquitocide Applications.	Dermal		MS	0.00088	210,000	X	2,300
		Inhalation		NA [2]	0.00060 (mg/m^3)	4,000	X	

TABLE 4—RESIDENTIAL POST-APPLICATION NON-CANCER EXPOSURE AND RISK ESTIMATES FOR CHLORPYRIFOS—Continued

Lifestage	Post-application exposure scenario		Application rate [1]	State (TTR data)	Dose (mg/kg/day) [3]	MOEs [4]	Combined routes [5]	Combined MOEs [6]
	Use site	Route of exposure						
		Hand-to-Mouth		MS	0.000018	5,600	X	
		Object-to-Mouth		MS	5.5×10^{-7}	180,000	NA	NA
		Soil Ingestion		NA [2]	1.2×10^{-7}	4,900,000	NA	NA
Adult (Females)		Dermal	0.010 (Ground)	MS	0.000074	520,000	X	1,200
		Inhalation		NA	0.0051 (mg/m^3)	1,200	X	
Children 1 to <2 yrs		Dermal		MS	0.00013	1,500,000	X	460
old.		Inhalation		NA	0.0051 (mg/m^3)	460	X	
		Hand-to-Mouth		MS	2.6×10^{-6}	39,000	X	
		Object-to-Mouth		MS	7.9×10^{-8}	1,300,000	NA	NA
		Soil Ingestion		NA [2]	1.7×10^{-8}	34,000,000	NA	NA

[1] Based on the maximum application rates registered for golf course turf and ULV mosquito adulticide uses.

[2] The airborne concentrations of chlorpyrifos following ULV mosquito adulticide applications was determined with use of the AgDISP (v8.2.6) model.

[3] Dose (mg/kg/day) equations for golfing and mosquitocide applications are provided in Appendices B and C (Ref. 1) of the updated occupational and residential exposures assessment. For calculation of doses (*i.e.,* dermal, hand-to-mouth, and object-to-mouth) from exposure to ULV mosquito adulticide, TTR data was used. The MS TTR data was selected for use because it is the worst case and, as a result, most protective of human health. Additionally, the fraction of chlorpyrifos residue deposited following mosquitocide application, 35% (0.35), was determined with use of the AgDISP (v8.2.6) model and used for dose calculation. The fraction of chlorpyrifos deposited following ground ULV application, 5% (0.050), is based on surrogate exposure data (malathion). For dose estimation from exposures to golfing on treated turf, on the TTR data was used. Doses have been presented for all State sites, including the mean of all State sites.

[4] MOE = PoD (mg/kg/day) ÷ Dose (mg/kg/day).

[5] X indicates the exposure scenario is included in the combined MOE; NA = Not applicable.

[6] Combined MOE = 1 ÷ (1/dermal MOE) + (1/inhalation MOE) + (1/incidental oral MOE), where applicable.

v. Aggregating exposures and developing the drinking water level of concern. Consistent with FFDCA section 408(b)(2)(D)(vi), EPA considers and aggregates (adds) pesticide exposures and risks from three major sources: Food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard, or the risks themselves can be aggregated. The durations of exposure identified for chlorpyrifos uses are acute and steady state. The acute aggregate assessment includes high end exposure values for food and drinking water but does not include residential exposure estimates. The steady state aggregate assessment includes food, drinking water, and residential exposures and for chlorpyrifos it is protective of the acute aggregate risks because examination indicates it results in higher risk estimates for all situations—so in effect acute residential exposures have also been considered in the aggregate risk assessment process.

For purposes of this proposed rule, EPA is using a DWLOC approach to aggregate risk. Under this approach, EPA calculates the amount of exposure available in the total 'risk cup' for chlorpyrifos oxon in drinking water after accounting for any chlorpyrifos exposures from food and/or residential use.

The DWLOC approach for this proposed rule uses a reciprocal MOE calculation method for adults (females of childbearing age) since the target MOEs are the same for all relevant sources of exposure, *i.e.,* 100X for residential dermal and for dietary food and water. This entails calculating the MOE for water (MOEwater) by deducting the contributions from food (MOEfood) and residential dermal exposure (MOEdermal) from the aggregate MOE (MOEagg) of 100. The aggregate MOE value is the same as target MOE (level of concern). The DWLOC is then calculated by dividing the PoDwater by the MOEwater. The general reciprocal MOE formula is as follows:

MOEagg = 1/((1/MOEwater) + (1/MOEfood) + (1/MOEdermal))

MOEwater = 1/((1/MOEagg) − ((1/MOEfood) + (1/MOEdermal)))

DWLOC= PoDwater/MOEwater

When target MOEs (levels of concern) are not the same across the relevant sources of exposure, the reciprocal MOE approach for calculating DWLOCs is not appropriate; instead an aggregate risk index (ARI) method is used. For purposes of this proposed rule, EPA therefore employed the ARI method for infants, children, and youths because the target MOEs for the relevant sources of exposure are not the same *i.e.,* the target MOE for dietary food and for residential dermal exposures is 40X while the target MOE for drinking water exposure is 50X. In this approach, the aggregate, or 'total', ARI value is assigned as 1 (EPA is generally concerned when any calculated ARIs are less than 1). Similar to the reciprocal MOE approach, the ARIs for food and dermal are deducted from the aggregate ARI to determine the ARI for water. The water ARI is multiplied by the target MOE for water to determine the calculated water MOE (MOEwater). The DWLOC is then calculated by dividing the PoDwater by the MOEwater. The general ARI method formula is as follows:

ARIs for food or dermal are calculated as ARIfood or dermal = (MOEfood or dermal)/(MOEtarget for food or dermal)).

ARIagg = 1/((1/ARIwater) + (1/ARIfood) + (1/ARIdermal))

ARIwater = 1/((1/ARIagg) − ((1/ARIfood) + (1/ARIdermal))); Where ARIagg = 1

MOEwater = ARIwater × MOEtarget.

DWLOC = PoDwater/MOEwater

Determination of Acute DWLOC. The acute aggregate assessment includes only food and drinking water. The acute DWLOCs were calculated for infants, children, youths, and adults and are presented in Table 5. The lowest acute DWLOC calculated was for infants (<1 year old) at 24 ppb. Acute exposures greater than 24 ppb are generally considered a risk concern and unsafe for purposes of FFDCA section 408(b).

TABLE 5—ACUTE AGGREGATE (FOOD AND DRINKING WATER) CALCULATION OF DWLOCS [1] [2]

Population	Food exposure (chlorpyrifos) [3]		Drinking water exposure (chlorpyrifos) [4]		Acute DWLOC [5] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	
Infants [1] (<1 yr)	2200	55	50	1.0	24
Children [1] (1–2 yrs)	1400	35	50	1.0	60
Youths [1] (6–12 yrs)	2800	70	50	1.0	150
Adults [2] (Females 13–49 yrs)	3100	NA	100	NA	53

[1] DWLOCs for infants, children and youths are calculated using the ARI (Aggregate Risk Index) approach since target MOEs are different for drinking water (chlorpyrifos oxon target MOE = 50) and for food and residential (chlorpyrifos target MOE = 40) exposure.
[2] DWLOCs for adults (females 13–49 years) are calculated using the reciprocal MOE approach since the target MOEs are the same for drinking water (chlorpyrifos oxon target MOE = 100) and for food and residential (chlorpyrifos target MOE = 100) exposure.
[3] FOOD: MOEfood = PoDfood (ug/kg/day) (from Table 4.8.4)/Food Exposure (ug/kg/day) (from Table 5.4.3). ARIfood = ((MOEfood)/(MOEtarget)).
[4] WATER (ARI approach): ARIwater = 1/((1/ARIagg) − ((1/ARIfood) + (1/ARIdermal))); Where ARIagg = 1 (Note: EPA is generally concerned when calculated ARIs are less than 1). MOEwater = ARIwater × MOEtarget. WATER (Reciprocal MOE approach): MOEwater = 1/((1/MOEagg) − ((1/MOEfood) + (1/MOEdermal))); Where MOEagg =Target MOE.
[5] DWLOC: DWLOC ppb = PoDwater (ppb; from Table 4.8.4)/MOEwater.

Determination of Steady State DWLOC. The steady state aggregate assessment includes dietary exposures from food and drinking water and dermal exposures from residential uses (dermal exposures represent the highest residential exposures). The steady state DWLOCs were calculated for infants, children, youths, and adults and are presented in Table 6. The lowest steady state DWLOC calculated was for infants (<1 year old) at 3.9 ppb. Exposures to chlorpyrifos oxon in drinking water at levels that exceed the steady state DWLOC of 3.9 ppb are therefore a risk concern and are considered unsafe for purposes of FFDCA section 408(b).

TABLE 6—STEADY STATE AGGREGATE (FOOD, DRINKING WATER, RESIDENTIAL) CALCULATION OF DWLOCS [1] [2]

Population	Food exposure (chlorpyrifos) [3]		Dermal exposure (chlorpyrifos) [4]		Drinking water exposure (chlorpyrifos oxon) [5]		Steady state DWLOC [6] (ppb chlorpyrifos oxon)
	MOE	ARI	MOE	ARI	MOE	ARI	
Infants [1] (<1 yr)	550	14	NA	NA	55	1.1	3.9
Children [1] (1–2 yrs)	410	10	NA	NA	55	1.1	10
Youths [1] (6–12 yrs)	700	18	1800	45	55	1.1	16
Adults [2] (Females 13–49 yrs)	1000	NA	1200	NA	120	NA	7.8

[1] DWLOCs for infants, children and youths are calculated using the ARI (Aggregate Risk Index) approach since target MOEs are different for drinking water (chlorpyrifos oxon target MOE = 50) and for food and residential (chlorpyrifos target MOE = 40) exposure.
[2] DWLOCs for adults (females 13–49 years) are calculated using the reciprocal MOE approach since the target MOEs are the same for drinking water (chlorpyrifos oxon target MOE = 100) and for food and residential (chlorpyrifos target MOE = 100) exposure.
[3] FOOD: MOEfood = PoDfood (ug/kg/day) (from Table 4.8.4)/Food Exposure (ug/kg/day) (from Table 5.4.4). ARIfood = ((MOEfood)/(MOEtarget)).
[4] DERMAL: MOEdermal = PoDdermal (ug/kg/day) (from Table 4.8.4)/Dermal Exposure (ug/kg/day) (from Table 6.2). ARIdermal = ((MOE dermal)/(MOEtarget)).
[5] WATER (ARI approach): ARIwater = 1/((1/ARIagg) − ((1/ARIfood) + (1/ARIdermal))); Where ARIagg = 1 (Note: EPA is generally concerned when calculated ARIs are less than 1). MOEwater = ARIwater × MOEtarget. WATER (Reciprocal MOE approach): MOEwater = 1/((1/MOEagg) − ((1/MOEfood) + (1/MOEdermal))); Where MOEagg = Target MOE.
[6] DWLOC: DWLOC ppb = PoDwater (ppb; from Table 4.8.4)/MOEwater.

vi. Estimating aggregate riskÐ comparing DWLOCs to estimated drinking water concentrations. In a DWLOC aggregate risk assessment, the calculated DWLOC is compared to the EDWC. When the EDWC is less than the DWLOC, there are no risk concerns for exposures to the pesticide in drinking water. Conversely, when the EDWC is greater than the DWLOC, there may be a risk concern. For chlorpyrifos, DWLOCs were calculated for both the acute and steady state aggregate assessments for infants, children, youths and adult females. However, for the national screening level drinking water assessment, only the steady state DWLOCs were compared to the modeled EDWCs (based on a national screen). The calculated steady state DWLOCs are much lower than those for the acute. For example, for infants, the lowest acute DWLOC is 24 ppb while the lowest steady state DWLOC is 3.9 ppb (Tables 5 and 6). Since the lowest DWLOC calculated for any duration or population was the 3.9 ppb steady state exposure value (infants), it is the concentration used for comparison to EPA's modeled EDWCs. Drinking water concentrations of chlorpyrifos oxon above 3.9 ppb may therefore be unsafe. Were EPA to conduct further analyses that compared all acute exposures to EDWC, it is possible that for some limited numbers of use scenarios, the EDWC could result in an exceedance of the acute DWLOC, but not the steady state DWLOC. However, because EPA is proposing to revoke all tolerances based on the steady state DWLOC, it is unnecessary to address that issue at this time.

EDWCs in Groundwater and Surface Water. EPA conducted a national screening level drinking water assessment for both groundwater and surface water, with focus on the agricultural uses. For both assessments, EPA calculated EDWCs for chlorpyrifos and chlorpyrifos oxon. Chlorpyrifos

EDWCs were multiplied by 0.9541 (molecular weight correction factor) and 100% (maximum conversion during water purification) to generate chlorpyrifos oxon EDWCs. EPA used a 100% conversion factor for the oxidation of chlorpyrifos to chlorpyrifos oxon as an approximation based on empirical bench scale laboratory data that indicate chlorpyrifos rapidly oxidizes to form chlorpyrifos oxon almost completely during typical water treatment (chlorination). (Ref. 77). There are limited data available on the removal efficiency of chlorpyrifos prior to oxidation or the removal efficiency of chlorpyrifos oxon during the drinking water treatment process. Based on community water systems survey showing that more than 75 percent of community water systems use chlorination to disinfect drinking water in the United States (Ref. 78), the assumption of exposure to chlorpyrifos oxon equivalent to 100% conversion of chlorpyrifos is not considered overly conservative. It is possible that some drinking water treatment procedures, such as granular activated carbon filtration and water softening (increased rate of chlorpyrifos oxon hydrolysis at pH > 9) could reduce the amount of chlorpyrifos oxon in finished drinking water; however, these treatment methods are not typical practices across the country for surface water.

While there is the potential to have both chlorpyrifos and chlorpyrifos oxon present in finished drinking water, no information is available to readily quantify how much of each form remains in the finished water. In the absence of available information, EPA conservatively assumes that 100% of chlorpyrifos that enters a drinking water treatment facility exists after treatment and that during treatment 100% of it converts to chlorpyrifos oxon.

Although chlorpyrifos oxon has a hydrolysis half-life of 5 days, the drinking water treatment simulation half-life for chlorpyrifos oxon is approximately 12 days. (Refs. 79, 80, and 81). Hydrolysis of chlorpyrifos oxon under simulated drinking water treatment processes is slower when compared to hydrolysis of chlorpyrifos oxon in water only; thus, the use of a half-life of 12 days under simulation. Therefore, once chlorpyrifos oxon forms during treatment, little transformation is expected to occur before consumption (during drinking water distribution). There are a wide range of treatment processes and sequences of treatment processes employed at community water systems across the country and there are limited data available on a community-water-system-specific basis to assess the removal or transformation of chlorpyrifos during treatment. These processes are not specifically designed to remove pesticides and pesticide transformation products including chlorpyrifos and chlorpyrifos oxon. In general, drinking water treatment processes, with the exception of activated carbon (Ref. 82), have been shown to have little impact on removal of conventional pesticides.

To illustrate the range of EDWC, two maximum label rate application scenarios were selected to represent high and low end exposures, *i.e.,* tart cherries at 5 applications totaling 14.5 pounds per acre per year, and bulb onions at a single application of one pound per acre per year, respectively. To estimate groundwater EDWCs for chlorpyrifos and chlorpyrifos oxon, EPA conducted a conservative Tier I assessment using SCI–GROW (Screening Concentration in Groundwater, version 2.3, August 8, 2003) and PRZM-Groundwater (PRZM–GW version 1.0, December 11, 2012), using the GW–GUI (Graphical User Interface, version 1.0, December 11, 2012). (Ref. 83). For this assessment, EPA used the results from the model (either SCI–GROW or PRZM–GW) that provided the highest EDWCs. Despite the conservative assumptions used in the Tier I models, as presented below in Table 7 estimated groundwater EDWCs are well below the DWLOCs and therefore do not represent a risk concern.

To calculate the national screening level surface water EDWCs for chlorpyrifos and chlorpyrifos oxon, EPA used the Tier II Surface Water Concentration Calculator (SWCC) version 1.106. The SWCC uses PRZM version 5.0+ (PRZM5) and the Variable Volume Water Body Model (VVWM). PRZM is used to simulate pesticide transport as a result of runoff and erosion from an agricultural field. VVWM estimates environmental fate and transport of pesticides in surface water. For the national screen, upper and lower bound exposure scenarios for surface water were modeled using the highest application rate (tart cherries), and the lowest application rate (bulb onions). This analysis showed that even with only one application, several chlorpyrifos uses may exceed the DWLOC at rates lower than maximum labeled rates (both single as well as yearly), including an application rate of one pound per acre per year. The analysis also showed that the DWLOC exceedances are not expected to be uniformly distributed across the country. The application of chlorpyrifos to tart cherries in Michigan resulted in concentrations that exceeded the drinking water level of concern (DWLOC); whereas, chlorpyrifos applications to bulb onions in Georgia resulted in concentrations below the DWLOC. To investigate with more specificity whether other chlorpyrifos application scenarios may result in concentrations that exceed the DWLOC, a screen (A risk assessment screen is a procedure designed to quickly separate out pesticides uses patterns that meet the safety standard from those that may not meet the safety standard) of all available surface water modeling scenarios was completed considering three different application dates and a single application at several different application rates that ranged from one to six pounds.

EPA also conducted a refined, but limited analysis of the spatial distribution of EDWCs at a regional level and at the drinking water intake level. This exercise demonstrated that chlorpyrifos applications will result in variable drinking water exposures that are highly localized, with concentrations of concern generally occurring in small watersheds where there is a high percent cropped area where chlorpyrifos use is expected.

Finally, EDWCs were also compared to monitoring data. This analysis showed that when modeling scenarios are parameterized to reflect reported use and EDWCs are adjusted to reflect percent cropped area, the EDWCs are within a range of 10x of the measured concentrations reported in the monitoring data. In addition, evaluation of the monitoring data further illustrates that exposures are highly localized. EPA is currently conducting a broader refined assessment that examines EDWCs on a regional and/or watershed scale to pin-point community drinking water systems where exposure to chlorpyrifos oxon as a result of chlorpyrifos applications may pose an exposure concern. As a result of the *PANNA* decision ordering EPA to respond to the PANNA–NRDC Petition by October 31, 2015, EPA has not been able to complete that assessment in advance of this proposed rule. EPA is continuing that assessment and will update this action with the results of that assessment, as warranted.

Estimated Aggregate RiskÐNational Drinking Water Screen Results. To determine whether the EDWC exceeds the steady state DWLOC of 3.9 ppb, as noted above, EPA initially conducted a bounding estimate of exposure using a screening level national assessment approach. The results of that exercise are reported in Table 7 for Tier I groundwater and Tier II surface water model simulations.

TABLE 7—ESTIMATED DRINKING WATER CONCENTRATIONS RESULTING FROM THE USE OF CHLORPYRIFOS

Residue	Surface water				Groundwater
	1-in-10 Year peak concentration ppb	21-Day average concentration ppb	1-in-10 Year annual average concentration ppb	30 Year annual average concentration ppb	SCI–GROW Tier I concentration ppb
Michigan Tart Cherries					
Chlorpyrifos	129	83.8	39.2	29.7	0.16
Chlorpyrifos-oxon	123	80.0	37.4	28.3	0.15
Georgia Onion					
Chlorpyrifos	6.2	3.1	1.2	0.8	0.01
Chlorpyrifos-oxon	5.9	3.0	1.1	0.8	0.01

SCI–GROW resulted in higher EDWCs than PRZM–GW simulations.

As Table 7 makes clear, the surface water EDWCs for the high application rate Michigan tart cherry scenario significantly exceed the steady state DWLOC of 3.9 ppb for chlorpyrifos oxon, while the low application rate Georgia bulb onion scenario results in EDWC below the DWLOC. Given that the results of the initial bounding estimate showed these mixed results, EPA conducted a further evaluation of additional use scenarios to determine which chlorpyrifos uses do and do not exceed the DWLOC, based on a single application of chlorpyrifos per year at 1 and 4 pounds (where permitted by labeling) of chlorpyrifos per acre. The results for 1 and 4 pounds per acre are reported here as a representation of what EPA believes to be the range of likely chlorpyrifos applications, bearing in mind that chlorpyrifos can be applied at lower and higher single rates (*e.g.,* an application rate of 6 pounds per acre on citrus). This analysis showed that the current maximum application rate scenarios, as well as maximum single application rates for a wide range of chlorpyrifos use scenarios, may result in a 21-day average concentration that exceeds the DWLOC. Table 8 represents the use scenarios that resulted in exceedances of the DWLOC from a single application to the crop and it shows the estimated percentage of 21-day intervals over a 30-year period for which the average concentration is expected to exceed the DWLOC.

TABLE 8—NATIONAL SCREENING RESULTS USING DWLOC APPROACH—SCENARIO REPRESENTATION AND LABELED RATE COMPARISON FOR EXAMPLE USES THAT EXCEED THE DWLOC

Scenario	Highest 21-day average concentration ppb (application date)	21-Day exceedance count	Represented use site examples (maximum single application rate)
		Percent [a]	
1 lb a.i./A			
MScornSTD	16.5 at 1.0 lb a.i./A	21	Corn [2 lb a.i./A (aerial and ground)].
TXcornOP	13.9 at 1.0 lb a.i./A	13	Soybean [1 lb a.i./A (aerial); 2.2 (ground)].
ILcornSTD	14.6 at 1.0 lb a.i./A	16	
MScotton	19.8 at 1.0 lb a.i./A [e]	16	Cotton [1 lb a.i./A (foliar aerial and ground); seed treatment
NCcotton	14.4 at 1.0 lb a.i./A	25	permitted at 2.2 lb a.i./A].
TXcotton	15.1 at 1.0 lb a.i./A	8	
NYgrape	15.7 at 1.0 lb a.i./A	27	Grape [2.25 lab a.i./A (ground)].
TXsorghumOP	25.8 at 1.0 lb a.i./A	12	Wheat [1 lb a.i./A (aerial and ground)].
			Sunflower [2 lb a.i./A (aerial and ground)].
TXwheatOP	21.0 at 1.0 lb a.i./A	6	*Other Grains:*
			Sorghum [3.3 lb a.i./A (granular) [b]].
			Alfalfa [1 lb a.i./A (aerial and ground)].
PAVegetableNMC	21.1 at 1.0 lb a.i./A	18	Vegetables and Ground Fruit:
			Strawberry [2 lb a.i./A (aerial and ground)].
			Radish [3 lb a.i./A (ground) [d]].
			Pepper [1 lb a.i./A (ground)] Onion [1 lb a.i./A (ground)].
CAlettuce	12.8 at 1.0 lb a.i./A	8	
MEpotato	10.7 at 1.0 lb a.i./A	17	*Other Row Crops:*
NCsweetpotatoSTD	13.5at 1.0 lb a.i./A	9	Tobacco [2 lb a.i./A (aerial and ground)].
			Sugarbeets [2 lb a.i./A (granular) [b]].
			Peanuts [4 lb a.i./A (granular) [c]] Sweet Potato [2 lb a.i./A (aerial and ground)].
2 lb a.i./A			
MIcherriesSTD	19.6 at 2.0 lb a.i./A	42	Orchards and Vineyards (Tree fruit and Nuts):
GApecansSTD	20.7 at 2.0 lb a.i./A	12	Fruit and Nuts [4 lb a.i./A (ground)].
			Pecans [2 lb a.i./A (air); 4.3 (ground)].

TABLE 8—NATIONAL SCREENING RESULTS USING DWLOC APPROACH—SCENARIO REPRESENTATION AND LABELED RATE COMPARISON FOR EXAMPLE USES THAT EXCEED THE DWLOC—Continued

Scenario	Highest 21-day average concentration ppb (application date)	21-Day exceedance count	Represented use site examples (maximum single application rate)
		Percent [a]	
PAapples	29.1 at 2.0 lb a.i./A	11	Apple [2 lb a.i./A (air and ground)]. Peach [2 lb a.i./A (air); 3 (ground)].
NCPeanutSTD	21.0 at 2.0 lb a.i./A	21	Peanut: 2.0 lb a.i./A (aerial and ground) 4 lb a.i./A (granular ground).
FLCitrusSTD	10.1 at 2.0 lb a.i./A	6	Citrus: 6.0 lb a.i./A [ground including airblast]. 2.3 lb a.i./A (aerial).

[a] The highest percent of 21-day time periods where the average concentration exceeds the DWLOC. There are approximately 10,000 21-day time periods per 30 year simulation; however, it should be noted that not all scenarios contain exactly 30 years of weather data.
[b] (1.0 (air and ground)).
[c] (2.0 (air and ground)).
[d] Incorporated or in furrow otherwise (1.0 (air and ground)).
[e] A preplant seed treatment is permitted at 2.2 lb a.i./A and assumes 100% of the applied material washes off the seed coat in the field and is available for transport.

In summary, EPA's analysis shows that the current maximum single application rates for a wide range of chlorpyrifos use scenarios result in a 21-day average concentration that exceeds the DWLOC. And the analysis makes clear that exceedances may occur with considerable frequency.

Regional Screen. Although Table 8 makes clear that numerous labeled chlorpyrifos uses result in exceedances of the DWLOC on a national basis, EPA analysis indicates that exposure is likely to be highly localized. While it is currently challenging to assess exposure on a local scale due to the unavailability of data and wide range of characteristics (*e.g.,* environmental characteristics such as soil, weather, etc. or other variables such as drinking water treatment processes) that affect the vulnerability of a given community drinking water system to chlorpyrifos oxon contamination, EPA developed a method to examine the potential geospatial concentration differences for two Hydrological Unit Code (HUC) 2 Regions—HUC 2 Region 17: Pacific Northwest and HUC 2 Region 3: South Atlantic-Gulf, in order to identify use patterns that may result in EDWCs that exceed the DWLOC on a regional basis. (Ref. 84). This analysis considered all potential chlorpyrifos use sites within the HUC 2 regions based on the National Agricultural Statistics Service cropland data layers and survey data. For HUC 2 Region 17, only four chlorpyrifos use patterns were identified as a potential concern based on maximum single application rates of 1 and 4 pounds per acre. However, for HUC 2 Region 3, several chlorpyrifos use scenarios were identified that could exceed the DWLOC, based on the use of available scenarios.

Watershed Screen. The uses that exceeded the DWLOC from the regional screening exercise for HUC 2 Region 3 were further explored by utilizing the DWI watershed database. This analysis shows an overlap of potential chlorpyrifos use sites that may result in an exceedance of the DWLOC with watersheds that supply source water for community drinking water systems. In addition, this analysis shows that exposure is not uniform within a HUC 2 Region and that some watersheds are more vulnerable than others. Watershed vulnerability is expected to be greatest for smaller watersheds with high percent cropped areas. Smaller community water systems are generally more vulnerable due to short distribution times and the reliance of chlorination to treat source surface water as well as limited access to other treatment methods such as granular activated carbon.

As noted above, on August 10, 2015, the *PANNA* decision ordered EPA to issue either a proposed or final revocation rule or a full and final response to PANNA–NRDC administrative Petition by October 31, 2015. As a result of that order, EPA is issuing this proposed revocation in advance of completing its refined drinking water assessment. As a result, EPA may update this action with a new or modified drinking water analyses as EPA completes additional work after this proposal.

Monitoring Data Analysis. In EPA's PHHRA in 2011, the agency evaluated water monitoring data from the USGS National Water Quality Assessment Program (NAWQA), USEPA/USGS Pilot Reservoir Monitoring Program, USDA PDP, and California Department of Pesticide Regulation (CDPR). The monitoring data showed chlorpyrifos detections at low concentrations, generally not exceeding 0.5 µg/L. For example, USGS NAWQA, which contains an extensive monitoring dataset for chlorpyrifos and chlorpyrifos oxon, reports a peak chlorpyrifos detection of 0.57 µg/L in surface water with a detection frequency of approximately 15%. CDPR has detected chlorpyrifos concentrations greater than 1 µg/L in surface water on several occasions, with an observed peak chlorpyrifos concentration of 3.96 µg/L. Sampling frequencies in these monitoring programs were sporadic, however, and generally range from only once per year to twice per month.

Since the preliminary assessment, EPA has evaluated additional water monitoring data from Washington State Department of Ecology and Agriculture (WSDE/WSDA) Cooperative Surface Water Monitoring Program (Refs. 85 and 86), Dow AgroSciences (Ref. 87), and Oregon Department of Environmental Quality. The previously referenced data have also been re-examined to consider short-term exposure (*i.e.,* 21-day average concentrations) considering the importance of the single day exposure and the temporal relationship of exposure. A summary of all surface water monitoring data examined to date for chlorpyrifos are presented in Table 9. Some of the monitoring programs analyzed for chlorpyrifos oxon; however, the number of detections as well as the concentrations were generally much lower. Since the majority of the conversion of chlorpyrifos to chlorpyrifos oxon is

assumed to occur during drinking water treatment, and not in the environment, the monitoring data presented in Table 9 are limited to chlorpyrifos and not its oxon.

TABLE 9—SURFACE WATER MONITORING DATA SUMMARY FOR CHLORPYRIFOS

Monitoring data	Scale	Years of sampling (number of samples)	Detection frequency (%)	Maximum concentration (µg/L)
USGS NAWQA	National	1991–2012 (30,542)	15	0.57
California Department of Pesticide Regulation.	State	1991–2012 (13,121)	20	3.96
Washington State Department of Ecology and Agriculture Cooperative Surface Water Monitoring Program.	State	2003–2013 (4,091)	8.4	0.4
USDA Pesticide Data Program	National	2004–2009 (raw water; 1,178) 2001–2009 (finished water; 2,918).	0	na
USGS–EPA Pilot Drinking Water Reservoir.	National	1999–2000 (323)	5.3	0.034
Oregon Department of Environmental Quality.	Watershed (Clackamas)	2005–2011 (363)	13	2.4
MRID 44711601 (Ref. 87)	Watershed (Orestimba Creek)	1996–1997 (1,089)	61	2.22

In general, the monitoring data include sampling sites that represent a wide range of aquatic environments including small and large water bodies, rivers, reservoirs, and urban and agricultural locations, but are limited for some areas of the United States where chlorpyrifos use occurs. Also, the sampling sites, as well as the number of samples, vary by year. In addition, the vulnerability of the sampling site to chlorpyrifos contamination varies substantially due to use, soil characteristics, weather and agronomic practices. While almost all samples in the monitoring results are below EPA's lowest DWLOC (infant steady state exposures) of 3.9 ppb, none of the monitoring programs examined to date were specifically designed to target chlorpyrifos use (except the Registrant Monitoring Program Ref. 87); therefore, peak concentrations (and likely 21-day average concentrations) of chlorpyrifos and chlorpyrifos oxon likely went undetected in these programs. See Table 9 for a summary of the chlorpyrifos surface water monitoring data.

As a general matter, sampling frequency needs to be approximately equal to the duration of exposure concern. (Ref. 88). The chlorpyrifos monitoring data evaluated thus far also show that as sample frequency increases, so does the detection frequency. This is evident in the registrant-submitted monitoring data, as well as examination of individual sampling sites within the various datasets. The highest detection frequency noted for chlorpyrifos is for Marion Drain (a sample site in Washington), where 103 samples were collected between 2006 and 2008, with 53 chlorpyrifos detections (51%).

Therefore, while there is a large number of individual samples collected and analyzed for chlorpyrifos (or chlorpyrifos oxon) across the United States, it would not be appropriate to combine these data sources to generate exposure estimates or to use these datasets to represent exposure on a national or even regional basis. Thus, comparing the monitoring data results to the DWLOC would not be a reasonable approach for the reasons given above, including limited sample frequency, limited use information, and sampling site variability, on a national or even a regional basis. EPA believes that model estimated concentrations provide more suitable upper bound concentrations for chlorpyrifos and chlorpyrifos oxon.

Additionally, model simulations were completed to represent two different water monitoring datasets—WSDE/WSDA Cooperative Surface Water Monitoring Program (Refs. 85 and 86) and Dow AgroSciences (Ref. 87) Orestimba Creek. For both of these water monitoring programs, enough information was available, including chlorpyrifos use information as well as the PCA, to parameterize the model. In these simulations, the modeled EDWCs were similar to the measured concentrations. This suggests that the modeling results are not overly conservative and supports the use of the model to estimate chlorpyrifos oxon concentrations in drinking water.

As noted above, EPA is continuing to work to refine its drinking water assessment with the goal of pinpointing regions or watersheds where EDWCs may exceed the DWLOC. This effort would include completing the regional assessment presented here for all HUC 2 Regions and crop uses, as well as considering multiple applications per year. Because of the *PANNA* decision ordering EPA to respond to the PANNA–NRDC Petition by October 31, 2015, EPA has not been able to complete this more refined drinking water assessment for chlorpyrifos in advance of this proposed rule. As a result, this proposal does not provide a basis for supporting a more tailored approach to risk mitigation. EPA is continuing to conduct its regional and water-intake level assessment and may update this action with the results of that assessment when it is completed.

Summary. EPA's examination of chlorpyrifos agricultural use across the country indicates that there are multiple uses of chlorpyrifos that may result in exposure to chlorpyrifos oxon in finished drinking water at levels that exceed the 21-day steady state DWLOC of 3.9 ppb for infants and children. EPA therefore believes that infants and children in some portions of the country are at some risk from cholinesterase inhibition. While there are uncertainties associated with the model input parameters for which conservative assumptions were made (*e.g.,* one aerobic aquatic metabolism half-life value multiplied by the uncertainty factor of three, stable to hydrolysis, 100% of the cropped watershed is treated, and use of the Index Reservoir as the receiving waterbody), the

modeling is sufficiently representative of some vulnerable water bodies that we cannot make a safety finding based on drinking water exposure. Comparison of model estimated concentrations with measured concentrations suggests that model estimates are consistent with measured concentrations when actual application rates and representative SWCC scenarios are considered and a PCA adjustment factor is applied to the model estimates. This modeling/monitoring comparison suggests that when growers use maximum application rates, or even rates much lower than maximum, chlorpyrifos oxon concentrations in drinking water could pose an exposure concern for a wide range of chlorpyrifos uses. However, these exposures are not expected to be uniformly distributed across the country. As noted, additional analyses are still being conducted in an effort to determine the community water systems where concentrations may be of concern. While that evaluation may ultimately lead to a more tailored approach to risk mitigation, at this point in time, based on the information before EPA, EPA cannot determine that current dietary exposures to chlorpyrifos are safe within the meaning of FFDCA section 408(b)(2)(A). Additionally, although EPA's current assessment indicates that the tolerances for food service and food handling establishments by themselves would not present an unsafe risk (since they do not result in drinking water exposure), because EPA must aggregate all dietary and non-occupational exposures to chlorpyrifos in making a safety finding under the FFDCA, EPA cannot find that any current tolerances are safe and is therefore proposing to revoke all chlorpyrifos tolerances. As noted, however, EPA is soliciting comment on whether it may be possible to retain some group of tolerances.

vii. Cumulative exposure/risk characterization. Section 408(b)(2)(D)(v) of the FFDCA provides that when determining the safety of a pesticide chemical, EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from the pesticide's residues when considered together with other substances that have a common mechanism of toxicity. Chlorpyrifos is a member of the OP class of pesticides, which share AChE inhibition as a common mechanism of toxicity. The agency completed a cumulative risk assessment for OPs in connection with FIFRA reregistration and FFDCA tolerance reassessment (Ref. 10) which can be found on EPA's Web site *http://www.epa.gov/pesticides/cumulative/rraop/.* To the extent that chlorpyrifos tolerances and uses remain following this action, prior to the completion of the FIFRA registration review for chlorpyrifos and the OP class, OPP will update the OP cumulative assessment to ensure that cumulative dietary exposures to the OPs are safe.

C. When do these actions become effective?

EPA is proposing that the revocation of the chlorpyrifos tolerances for all commodities become effective 180 days after a final rule is published. The agency believes this revocation date will allow users to exhaust stocks and allow sufficient time for passage of treated commodities through the channels of trade. However, if EPA is presented with information that unused stocks would still be available and that information is verified, the agency will consider extending the expiration date of associated tolerances. If you have comments regarding stocks of remaining chlorpyrifos products and whether the effective date allows sufficient time for treated commodities to clear the channels of trade, please submit comments as described under **SUPPLEMENTARY INFORMATION.**

Any commodities listed in this proposal treated with the pesticides subject to this proposal, and in the channels of trade following the tolerance revocations, shall be subject to FFDCA section 408(1)(5), as established by FQPA. That section provides that, any residues of the subject pesticide in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and

2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance. Evidence to show that food was lawfully treated may include records that verify the dates when the pesticide was applied to such food.

VII. International Residue Limits and Trade Considerations

The tolerance revocations in this proposal are not discriminatory and are designed to ensure that both domestically-produced and imported foods meet the food safety standard established by the FFDCA. The same food safety standards apply to domestically produced and imported foods.

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party.

EPA also ensures that its tolerance decisions are in keeping with the World Trade Organization's Sanitary and Phytosanitary Measures Agreement. Consistent with that agreement, the effective date EPA is proposing for the revocation of chlorpyrifos tolerances in this proposed rule ensures that the tolerances will remain in effect for a period sufficient to allow a reasonable interval for producers in the exporting countries to adapt to the requirements of these modified tolerances.

VIII. Statutory and Executive Order Reviews

In this proposed rule, EPA is proposing to revoke specific tolerances established under FFDCA section 408. The Office of Management and Budget (OMB) has exempted this type of action (*e.g.,* tolerance revocation for which extraordinary circumstances do not exist) from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866, this proposed rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001).

This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). Nor does it require any special considerations as required by Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income

Populations'' (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). However, EPA considered the best available science in order to protect children against environmental health risks and this proposed rule is consistent with EPA's 1995 Policy on Evaluating Health Risks to Children (*http://www2.epa.gov/sites/production/files/201405/documents/1995_childrens_health_policy_statement.pdf*), reaffirmed in 2013 (*http://www2.epa.gov/sites/production/files/201405/documents/reaffirmation_memorandum.pdf*).

This proposed rule does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note). In addition, the Agency has determined that this proposed rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999). This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This proposed rule does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000).

I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.* The small entities subject to this proposed action, which directly regulates growers, food processors, food handlers, and food retailers, include small businesses but not small government jurisdiction or small not-for-profit organizations as defined by the RFA.

For purposes of assessing the impacts of this proposed revocation on small businesses, a small business is defined either by the number of employees or by the annual dollar amount of sales/revenues. The level at which an entity is considered small is determined for each NAICS code by the Small Business Administration (SBA). Farms are classified under NAICS code 111, Crop Production, and the SBA defines small entities as farms with total annual sales of $750,000 or less.

Based upon the screening analysis completed (Ref. 89), EPA has determined that less than 39,000 of the 1.2 million small farms nationwide, or approximately 3% of all small farms, may be impacted by this proposed revocation. Of these, 38,000 have potential impacts of less than 1% of gross farm revenue. The analysis indicates that fewer than 1,000 small farms, or 0.1% percent of all small farms, may experience impacts greater than 1%, depending on the availability and cost of alternatives. Based on this analysis, EPA concludes that revoking all tolerances for chlorpyrifos will not have a significant economic impact on a substantial number of small entities. Details of this analysis are presented in EPA's analyses which can be found in the docket (Ref. 89).

IX. References

EPA has established an official record for this rulemaking. The official record includes all information considered by EPA in developing this proposed rule including documents specifically referenced in this action and listed below, any public comments received during an applicable comment period, and any other information related to this action, including any information claimed as CBI. This official record includes all information physically located in docket ID number EPA–HQ–OPP–2015–0653, any documents identified in this proposal, and documents referenced in documents in the docket. The public version of the official record does not include any information claimed as CBI.

1. U.S. EPA (2014). Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review. Available in docket number EPA–HQ–OPP–2008–0850, *http://www.regulations gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0195.*
2. The Petition from NRDC and PANNA and EPA's various responses to it are available in docket number EPA–HQ–OPP–2007–1005 available at *www.regulations.gov.*
3. U.S. EPA (2011). Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review. Available in docket number EPA–HQ–OPP–2008–0850, *http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0025.*
4. Information and software related to Dietary Exposure Evaluation Model and the Calendex models is available at *http://www.epa.gov/pesticides/science/deem/.*
5. For information related to Section 408 of FFDCA see *http://www2.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act.*
6. For information on the EPA's Office of Pesticide Programs risk assessment process see *http://www.epa.gov/pesticides/about/overview_risk_assess.htm.*
7. U.S. EPA (2000). Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern. Available at *http://www.epa.gov/oppfead1/trac/science/trac2b054.pdf.*
8. Information on the water exposure models used by EPA's Office of Pesticide Programs is available at *http://www.epa.gov/oppefed1/models/water/models4.htm.*
9. FIFRA Scientific Advisory Panel (2008). ''The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos.'' Report from the FIFRA Scientific Advisory Panel Meeting of September 16–19, 2008. Available: *http://www2.epa.gov/sap/fifra-scientific-advisory-panel-meetings.*
10. FIFRA Scientific Advisory Panel (2012). ''Scientific Issues Associated with Chlorpyrifos''. Available at: *http://www2.epa.gov/sap/meeting-materials-april-10-12-2012-scientific-advisory-panel.*
11. FIFRA Scientific Advisory Panel (2002). ''Organophosphate Pesticides: Preliminary OP Cumulative Risk Assessment.'' Information on how to obtain the meeting report is available at *http://www2.epa.gov/sap/fifra-scientific-advisory-panel-meetings.*
12. U.S. EPA (2006). Revised Organophosphorous Pesticide Cumulative Risk Assessment. Available at *http://www.epa.gov/pesticides/cumulative/2006-op/index.htm.*
13. Chambers, J.E. (2013). *In vitro* Sensitivity of Cholinesterase to Inhibition by Chlorpyrifos-oxon in Several Tissues of the Rat. College of Veterinary Medicine, Mississippi State University.
14. Calhoun LL, Johnson KA. (1988) Chlorpyrifos: 4-Day Dermal Probe and 21-Day Dermal Toxicity Studies in Fischer 344 Rats. MRID 40972801.
15. Corley, R.; Landry, T.; Calhoun, L.; *et al.* (1986) Chlorpyrifos: 13-Week Nose-only Vapor Inhalation Exposure Study in Fischer 344 Rats. MRID 40013901.
16. Corley, R.; Landry, T.; Calhoun, L.; *et al.* (1986) Chlorpyrifos: 13-Week Nose-only Vapor Inhalation Exposure Study in Fischer 344 Rats: Supplemental Data: Lab. MRID 40166501.
17. Newton, P. (1988) AThirteen Week Nose-Only Inhalation Toxicity Study of Chlorpyrifos Technical (Pyrinex) in the Rat. MRID 40908401.
18. Hotchkiss, J.; Krieger, S.; Brzak, K.; *et al.* (2010) Acute Inhalation Exposure of Adult Crl: CD (SD) Rats to Particulate Chlorpyrifos Aerosols: Kinetics of Concentration-Dependent Cholinesterase (ChE) Inhibition in Red Blood Cells, Plasma, Brain, and Lung. MRID 48139303.

19. U.S. EPA (2011) Chlorpyrifos: Review of the Comparative Cholinesterase (including chlorpyrifos oxon), special acute inhalation study and immunotoxicity studies (MRIDs 48139301, 48139303, 48139304). TXR No. 0055409.
20. Hotchkiss, J.; Krieger, S.; Mahoney, K.; *et al.* (2013) Nose-only Inhalation of Chlorpyrifos Vapor: Limited Toxicokinetics and Determination of Time-dependent Effects on Plasma, Red Blood Cell, Brain and Lung Cholinesterase Activity in Femal CD(SD): Crl Rats. MRID 49119501.
21. Hotchkiss, J.; Krieger, S.; Mahoney, K.; *et al.* (2013) Nose-Only Inhalation of Chlorpyrifos-Oxon Vapor: Limited Toxicokinetics and Determination of Time-Dependent Effects on Plasma, Red Blood Cell, Brain and Lung Cholinesterase Activity in Female CD(SD): Crl Rats. MRID 49210101.
22. U.S. EPA (2002). Revised Organophosphorous Pesticide Cumulative Risk Assessment. Available at *http://www.epa.gov/pesticides/cumulative/rra-op/.*
23. U.S. EPA (2006). Approaches for the Application of Physiologically Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment. Available at *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=157668.*
24. Timchalk, C., *et al.,* 2002a. Monte Carlo analysis of the human chlorpyrifos-oxonase (PON1) polymorphism using a physiologically based pharmacokinetic and pharmacodynamic (PBPK/PD) model. Toxicology Letters. 135, 51.
25. Timchalk, C., *et al.,* 2002b. A Physiologically based pharmacokinetic and pharmacodynamic (PBPK/PD) model for the organophosphate insecticide chlorpyrifos in rats and humans. Toxicological Sciences. 66, 34–53.
26. U.S EPA FIFRA Scientific Advisory Panel. (2011). ''Chlorpyrifos Physiologically Based Pharmacokinetic and Pharmacodynamic (PBPK–PD) Modeling linked to Cumulative and Aggregate Risk Evaluation System (CARES).'' Report from the FIFRA Scientific Advisory Panel Meeting of February 15–18, 2011. Available at *http://www2.epa.gov/sap/fifra-scientific-advisory-panel-meetings.*
27. U.S. EPA 2014. Chlorpyrifos: Quality Assurance Assessment of the Chlorpyrifos Physiologically Based Pharmacokinetic/Pharmacodynamic Model for Human Health Risk Assessment Applications. TXR No. 0056896. Available at *http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0843.*
28. U.S. EPA. Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R–09/052F, 2011. Available at *http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252.*
29. NHANES/WWEIA survey and supporting documentation is available at *http://www.ars.usda.gov/Services/docs.htm?docid=13793.*
30. US EPA (2012). Standard Operating Procedures for Residential Pesticide Exposure Assessment available at *http://www.epa.gov/pesticides/science/USEPA-OPP-HED_Residential%20SOPs_Oct2012.pdf.*
31. Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation Available at *http://www2.epa.gov/osa/guidance-applying-quantitative-data-develop-data-derived-extrapolation-factors-interspecies-and.*
32. Dow AgroSciences (2014), P. Price. Development of Chemical Specific Adjustment Factors for Chlorpyrifos and Chlorpyrifos Oxon Using Target Red Blood Cell Acetyl Cholinesterase Inhibition Levels of 10%, 5%, and 1%. Available at *http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0218.*
33. U.S. EPA (2002). Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment. Available at *http://www.epa.gov/oppfead1/trac/science/determ.pdf).*
34. Aldridge, J. E., Levin, E. D., Seidler, F. J., & Slotkin, T. A. (2005). Developmental exposure of rats to chlorpyrifos leads to behavioral alterations in adulthood, involving serotonergic mechanisms and resembling animal models of depression. Environ Health Perspect, 113(5), 527–531.
35. Icenogle, L. M., Christopher, N. C., Blackwelder, W. P., Caldwell, D. P., Qiao, D., Seidler, F. J., *et al.* (2004). Behavioral alterations in adolescent and adult rats caused by a brief subtoxic exposure to chlorpyrifos during neurulation. Neurotoxicol Teratol, 26(1), 95–101.
36. Levin, E. D., Addy, N., Baruah, A., Elias, A., Christopher, N. C., Seidler, F. J., *et al.* (2002). Prenatal chlorpyrifos exposure in rats causes persistent behavioral alterations. Neurotoxicol Teratol, 24(6), 733–741.
37. Levin, E. D., Addy, N., Nakajima, A., Christopher, N. C., Seidler, F. J., & Slotkin, T. A. (2001). Persistent behavioral consequences of neonatal chlorpyrifos exposure in rats. Brain Res Dev Brain Res, 130(1), 83–89.
38. Billauer-Haimovitch, H., Slotkin, T. A., Dotan, S., Langford, R., Pinkas, A., & Yanai, J. (2009). Reversal of chlorpyrifos neurobehavioral teratogenicity in mice by nicotine administration and neural stem cell transplantation. Behav Brain Res, 205(2), 499–504.
39. Jett, D. A., Navoa, R. V., Beckles, R. A., & McLemore, G. L. (2001). Cognitive function and cholinergic neurochemistry in weanling rats exposed to chlorpyrifos. Toxicol Appl Pharmacol, 174(2), 89–98.
40. Turgeman, G., Pinkas, A., Slotkin, T. A., Tfilin, M., Langford, R., & Yanai, J. (2011). Reversal of chlorpyrifos neurobehavioral teratogenicity in mice by allographic transplantation of adult subventricular zone-derived neural stem cells. J Neurosci Res, 89(8), 1185–1193.
41. Slotkin TA, Card J, Infante A, Seidler FJ. (2013) Prenatal dexamethasone augments the sex-selective developmental neurotoxicity of chlorpyrifos: Implications for vulnerability after pharmacotherapy for preterm labor. Neurotoxicol Teratol. 37:1–12.
42. Ohishi T, Wang L, Akane H, Itahashi M, Nakamura D, Yafune A, Mitsumori K, Shibutani M. (2013). Reversible effect of maternal exposure to chlorpyrifos on the intermediate granule cell progenitors in the hippocampal dentate gyrus of rat offspring. Reprod. Toxicol. 35:125–136.
43. Berkowitz, G. S., Obel, J., Deych, E., Lapinski, R., Godbold, J., Liu, Z., Wolff, M. S. (2003). Exposure to indoor pesticides during pregnancy in a multiethnic, urban cohort. Environ Health Perspect, 111(1), 79–84.
44. Whyatt, R. M., Barr, D. B., Camann, D. E., Kinney, P. L., Barr, J. R., Andrews, H. F., . . . Perera, F. P. (2003). Contemporary-use pesticides in personal air samples during pregnancy and blood samples at delivery among urban minority mothers and newborns. Environ Health Perspect, 111(5), 749–756.
45. Whyatt, R. M., Garfinkel, R., Hoepner, L. A., Andrews, H., Holmes, D., Williams, M. K., . . . Barr, D. B. (2009). A biomarker validation study of prenatal chlorpyrifos exposure within an inner-city cohort during pregnancy. Environ Health Perspect, 117(4), 559–567.
46. Whyatt, R. M., Garfinkel, R., Hoepner, L. A., Holmes, D., Borjas, M., Williams, M. K., . . . Camann, D. E. (2007). Within- and between-home variability in indoor-air insecticide levels during pregnancy among an inner-city cohort from New York City. Environ Health Perspect, 115(3), 383–389.
47. Bradman, A., Whitaker, D., Quiros, L., Castorina, R., Claus Henn, B., Nishioka, M., . . . Eskenazi, B. (2007). Pesticides and their metabolites in the homes and urine of farmworker children living in the Salinas Valley, CA. J Expo Sci Environ Epidemiol, 17(4), 331–349. doi: 10.1038/sj.jes.7500507.
48. Engel SM, Berkowitz GS, Barr DB, Teitelbaum SL, Siskind J, Meisel SJ, Wetmur JG, Wolff MS. Prenatal Organophosphate Metabolite and Organochlorine Levels and Performance on the Brazelton Neonatal Behavioral Assessment Scale in a Multiethnic Pregnancy Cohort. American Journal of Epidemiology. 2007;165:1397–1404.
49. Young, J. G., Eskenazi, B., Gladstone, E. A., Bradman, A., Pedersen, L., Johnson, C., . . . Holland, N. T. (2005). Association between in utero organophosphate pesticide exposure and abnormal reflexes in neonates. Neurotoxicology, 26(2), 199–209. doi: 10.1016/j.neuro.2004.10.004.
50. Rauh, V. A., Garfinkel, R., Perera, F. P., Andrews, H. F., Hoepner, L., Barr, D. B., . . . Whyatt, R. W. (2006). Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children. Pediatrics, 118(6), e1845–1859.
51. Whyatt, R. M., Rauh, V., Barr, D. B., Camann, D. E., Andrews, H. F., Garfinkel, R., . . . Perera, F. P. (2004).

Prenatal insecticide exposures and birth weight and length among an urban minority cohort. Environ Health Perspect, 112(10), 1125–1132.
52. Engel, S. M., Wetmur, J., Chen, J., Zhu, C., Barr, D. B., Canfield, R. L., & Wolff, M. S. (2011). Prenatal exposure to organophosphates, paraoxonase 1, and cognitive development in childhood. Environ Health Perspect, 119(8), 1182–1188. doi: 10.1289/ehp.1003183.
53. Eskenazi, B., Marks, A. R., Bradman, A., Harley, K., Barr, D. B., Johnson, C., . . . Jewell, N. P. (2007). Organophosphate pesticide exposure and neurodevelopment in young Mexican-American children. Environ Health Perspect, 115(5), 792–798. doi: 10.1289/ehp.9828.
54. Eskenazi, B., Huen, K., Marks, A., Harley, K. G., Bradman, A., Barr, D. B., & Holland, N. (2010). PON1 and neurodevelopment in children from the CHAMACOS study exposed to organophosphate pesticides in utero. Environ Health Perspect, 118(12), 1775–1781. doi: 10.1289/ehp.1002234.
55. Furlong, Melissa A., Engel, Stephanie M., Boyd Barr, Dana, Wolff, Mary S. Prenatal exposure to organophosphate pesticides and reciprocal social behavior in childhood. 2014. Environment International 70:125–131.
56. Rauh, V., Arunajadai, S., Horton, M., Perera, F., Hoepner, L., Barr, D. B., & Whyatt, R. (2011). Seven-year neurodevelopmental scores and prenatal exposure to chlorpyrifos, a common agricultural pesticide. Environ Health Perspect, 119(8), 1196–1201.
57. Bouchard, M. F., Chevrier, J., Harley, K. G., Kogut, K., Vedar, M., Calderon, N., . . . Eskenazi, B. (2011). Prenatal exposure to organophosphate pesticides and IQ in 7-year-old children. Environ Health Perspect, 119(8), 1189–1195. doi: 10.1289/ehp.1003185.
58. Rauh, V. A., Perera, F. P., Horton, M. K., Whyatt, R. M., Bansal, R., Hao, X., . . . Peterson, B. S. (2012). Brain anomalies in children exposed prenatally to a common organophosphate pesticide. Proc Natl Acad Sci U S A, 109(20), 7871–7876. doi: 10.1073/pnas.1203396109.
59. The Federal Letter- Review of Chlorpyrifos Epidemiology Studies is available at *http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0170.*
60. Billauer-Haimovitch, H., Slotkin, T. A., Dotan, S., Langford, R., Pinkas, A., & Yanai, J. (2009). Reversal of chlorpyrifos neurobehavioral teratogenicity in mice by nicotine administration and neural stem cell transplantation. Behav Brain Res, 205(2), 499–504.
61. U.S.EPA (1998). Guidelines for Neurotoxicity RiskAssessment. Available at *http://archive.epa.gov/raf/web/pdf/neurotox.pdf.*
62. Ricceri, L., Markina, N., Valanzano, A., Fortuna, S., Cometa, M. F., Meneguz, A., *et al.* (2003). Developmental exposure to chlorpyrifos alters reactivity to environmental and social cues in adolescent mice. Toxicol Appl Pharmacol, 191(3), 189–201.
63. Venerosi, A., Calamandrei, G., & Ricceri, L. (2006). A social recognition test for female mice reveals behavioral effects of developmental chlorpyrifos exposure. Neurotoxicol Teratol, 28(4), 466–471.
64. Venerosi, A., Ricceri, L., Rungi, A., Sanghez, V., & Calamandrei, G. (2010). Gestational exposure to the organophosphate chlorpyrifos alters social-emotional behaviour and impairs responsiveness to the serotonin transporter inhibitor fluvoxamine in mice. Psychopharmacology (Berl), 208(1), 99–107.
65. Hoberman, A. (1999) Developmental Neurotoxicity Study of Chlorpyrifos Administered Orally via Gavage to Crl: CDBR VAF/Plus Presumed Pregnant Rats: Report Supplement 2: Lab Project Number: 301–001: K–044739–109. Unpublished study prepared by Argus Research Laboratories, Inc. (MRID 44787301).
66. Chen X-P, Chen W-Z, Wang F-;S, Liu J-X. (2012) Selective cognitive impairments are related to selective hippocampus and prefrontal cortex deficits after prenatal chlorpyrifos exposure. Brain Res. 1474:19–28.
67. Bouchard MF, Bellinger DC, Wright RO, Weisskopf MG. (2010). Attention-deficit/hyperactivity disorder and urinary metabolites of organophosphate pesticides.Pediatrics. 2010 Jun;125(6):e1270–7. doi: 10.1542/peds.2009–3058.
68. Rauh, V. A., Perera, F. P., Horton, M. K., Whyatt, R. M., Bansal, R., Hao, X., . . . Peterson, B. S. (2012). Brain anomalies in children exposed prenatally to a common organophosphate pesticide. Proc Natl Acad Sci U S A, 109(20), 7871–7876.
69. Lovasi, G. S., Quinn, J. W., Rauh, V. A., Perera, F. P., Andrews, H. F., Garfinkel, R., . . . Rundle, A. (2011). Chlorpyrifos exposure and urban residential environment characteristics as determinants of early childhood neurodevelopment. Am J Public Health, 101(1), 63–70.
70. U.S. EPA (2014). Chlorpyrifos: Updated Drinking Water Assessment for Registration Review. Available in docket number EPA–HQ–OPP–2008–0850, *http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0198.*
71. U.S. EPA (2002). Aggregate Risk Assessment for Trichloropyridinol (TCP) Metabolite of Triclopyr (PC Code 116001), Chlorpyrifos (PC Code 059101), and Chlorpyrifos-methyl (PC Code 059102). Barcode D283101.
72. U.S. EPA (2011). Chlorpyrifos: Revised Acute (Probabilistic) and Chronic Dietary Exposure and Risk Assessments for Food only (with and without Food Handling Use included) and for Water Only for the Registration Review Action—Typical Use Rates/Water Included. D388166.
73. U.S. EPA (2014). Usage Report in Support of Chlorpyrifos (059101). Available at *www.regulations.gov* in docket number EPA–HQ–OPP–2008–0850.
74. U.S. EPA (2014). Chlorpyrifos: Updated Occupational and Residential Exposure Assessment for Registration Review. D424484. Available at *http://www.regulations.gov/#!document Detail;D=EPA-HQ-OPP-2008-0850-0196.*
75. J.C. Moore, J.C. Dukes, J.R. Clark, J. Malone, C.F. Hallmon, and P.G. Hester. Downwind Drift and Deposition of Malathion on Human Targets From Ground Ultra-Low Volume Mosquito Sprays; Journal of the American Mosquito Control Association; Vol. 9, No. 2 (June, 1993).
76. N.S. Tietze, P.G. Hester, and K.R. Shaffer. Mass Recovery of Malathion in Simulated Open Field Mosquito Adulticide Tests: Archives of Environmental Contamination and Toxicology; 26: 473–477 (1994).
77. Duirk, S. E.; Collette, T. W.; Degradation of Chlorpyrifos in Aqueous Chlorine Solutions: Pathways, Kinetics, and Modeling. Environ. Sci. Technol., 2006, 40(2), 546–550.
78. Community Water System Survey 2006; U.S. Environmental Protection Agency, Washington, DC 20460 May 2009 (survey data) available at *http://www.epa.gov/oppefed1/models/water/Development_and_Use_of_Community_Water_System.pdf.*
79. Tunink, A. Chlorpyrifos-oxon: Determination of hydrolysis as a function of pH, 2010. (MRID 48355201)
80. Wu, J.; Laird, D. A. Abiotic Transformation of Chlorpyrifos to Chlorpyrifos Oxon in Chlorinated Water. Environ. Toxcol. Chem., 2003, 22(2), 261–264.
81. Tierney, D. P.; Christensen, B. R.; Culpepper, V. C. Chlorine Degradation of Six Organophosphate Insecticides and Four Oxons in Drinking Water Matrix. Submitted by Syngenta Crop Protection, Inc. 2001. (MRID 45513501)
82. Progress Report on Estimating Pesticide Concentrations in Drinking Water and Assessing Water Treatment Effects on Pesticide Removal and Transformation: A Consultation. FIFRA Scientific Advisory Panel Meeting, September 29, 2000. Information on obtaining the report is available at *http://www2.epa.gov/sap/fifra-scientific-advisory-panel-meetings.*
83. To access EPA's water models go to *http://www.epa.gov/oppefed1/models/water/.*
84. Additional information related to HUCs can be found at *http://water.usgs.gov/GIS/huc.html.*
85. Sargeant, D., Dugger, D., Newell, E., Anderson, P., Cowles, J. Surface Water Monitoring Program for Pesticides in Salmonid-Bearing Streams 2006–2008 Triennial Report, February 2010 (Washington State Department of Ecology and Washington State Department of Agriculture) *https://fortress.wa.gov/ecy/publications/summarypages/1003008.html; http://agr.wa.gov/PestFert/natresources/docs/swm/2008_swm_report.pdf.*
86. Sargeant, D., Newell, E., Anderson, P., Cook, A. Surface Water Monitoring Program for Pesticides in Salmonid-Bearing Streams 2009–2011 Triennial

Report, February 2013 (Washington State Department of Ecology and Washington State Department of Agriculture) *http://agr.wa.gov/FP/Pubs/docs/377-SWM2009-11Report.pdf.*

87. Poletika, N.; Robb, C. (1998) A Monitoring Study to Characterize Chlorpyrifos Concentration Patterns and Ecological Risk in an Agriculturally Dominated Tributary of San Joaquin River: Lab Project Number: ENV96055. Unpublished study prepared by Dow AgroSciences and Paragon Research. (MRID 44711601).
88. U.S. EPA (2012). FIFRA SAP: Problem Formulation for the Reassessment of Ecological Risks from the Use of Atrazine, June 12–14, 2012, Docket Number: EPA–HQ–OPP–2012–0230 at *www.regulations.gov.*
89. U.S. EPA (2015). Analysis of the Small Business Impacts of Revoking Chlorpyrifos Food Tolerances. Available at *www.regulations.gov* in docket number EPA–HQ–OPP–2015–0653.
90. U.S. EPA (2014). Chlorpyrifos Acute and Steady State Dietary (Food Only) Exposure Analysis to Support Registration Review. Available at *www.regulations.gov* in docket number EPA–HQ–OPP–2008–0850.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 28, 2015.

Jack E. Housenger,

Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

§ 180.342 [Removed]

■ 2. Remove § 180.342.

[FR Doc. 2015–28083 Filed 11–5–15; 8:45 am]

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Vol. 80, No. 215

Friday, November 6, 2015

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FEDERAL REGISTER PAGES AND DATE, NOVEMBER

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

361.....67261
363.....67261
364.....67261
365.....67261
367.....67261
369.....67261
370.....67261
373.....67261
377.....67261
380.....67261
381.....67261
385.....67261
396.....67261
400.....67261
426.....67261
460.....67261
491.....67261
535.....67261
606.....67261
607.....67261
608.....67261
609.....67261
611.....67261
614.....67261
628.....67261
636.....67261
637.....67261
642.....67261
643.....67261
644.....67261
645.....67261
646.....67261
647.....67261
648.....67261
650.....67261
654.....67261
655.....67261
661.....67261
662.....67261
663.....67261
664.....67261
682.....67261
692.....67261
694.....67261
1100.....67261

36 CFR

242.....68245, 68249

37 CFR

Proposed Rules:
42.....67680

38 CFR

17.....68447

Proposed Rules:
17.....68479
74.....68795

39 CFR

Proposed Rules:
3050.....68480

40 CFR

52 .....67319, 67335, 67642, 67645, 67647, 67652, 68253, 68448, 68451, 68453, 68458, 68766, 68768
81.....67652, 68253
170.....67496
180 .....68257, 68261, 68772
423.....67838

Proposed Rules:
52 .....67681, 67682, 68481, 68484, 68486, 68807
60.....68808
180.....68289, 69080
260.....68490
261.....68490, 68491
262.....68490, 68491
263.....68490
264.....68490
265.....68490
266.....68491
268.....68490, 68491
270.....68490
273.....68490, 68491
279.....68490

42 CFR

409.....68624
413.....68968
424.....68624
447.....67576
484.....68624

Proposed Rules:
447.....67377
482.....68126
484.....68126
485.....68126

43 CFR

10.....68465

45 CFR

Proposed Rules:
95.....68290
1355.....68290
1356.....68290

46 CFR

515.....68722

47 CFR

1.....67337
2.....68471
73.....67337, 67344

Proposed Rules:
1.....67689, 68815
4.....67689
25.....68815
73.....68815
74.....68815

48 CFR

1817.....68778
1852.....68778

50 CFR

100.....68245, 68249
635.....68265
648.....67664
660.....67664
665.....68778
679.....67346, 68267

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List November 4, 2015

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